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**UNITED STATES DISTRICT COURT
 DISTRICT OF NEW JERSEY**

BOARD OF TRUSTEES OF HEAVY	:	Civil Action No.
AND GENERAL LABORERS’ LOCAL	:	
UNIONS 472 AND 172 OF NJ	:	
WELFARE FUND, on behalf of itself and	:	
all others similarly situated,	:	
	:	
<i>Plaintiff,</i>	:	COMPLAINT and
	:	DEMAND FOR JURY TRIAL
v.	:	
	:	
	:	
AMARIN PHARMA, INC., AMARIN	:	
PHARMACEUTICALS IRELAND	:	
LIMITED, AND AMARIN	:	
CORPORATION PLC,	:	
	:	
<i>Defendants.</i>	:	

Plaintiff Board of Trustees of the Heavy and General Laborers’ Local Unions 472 and 172 of NJ Welfare Fund (“Plaintiff”) on behalf of itself and all others similarly situated brings this action against Amarin Pharma, Inc., Amarin Pharmaceuticals Ireland Limited, and Amarin Corporation PLC (collectively “Amarin”) and alleges as follows:

INTRODUCTION

1. This action arises from Defendants’ illegal scheme to delay competition in the marketing and sale of Vascepa in the United States. Vascepa is a prescription medication

approved by the U.S. Food and Drug Administration (“FDA”) to treat hypertriglyceridemia in adults. As a result of Amarin’s sham patent litigation against generic drug manufacturers, which delayed the regulatory approval and launch of generic versions of Vascepa and from Amarin’s unlawful prevention of generic competition for Vascepa by precluding access to the world’s supply of the active pharmaceutical ingredient needed to make the drug, Plaintiff and the Classes it represents have been harmed in their business and property.

2. The key ingredient in Vascepa is icosapent ethyl (“IPE”), made from eicosapentaenoic acid (“EPA”), an omega-3 fatty acid found in fish oil. Vascepa has been shown both to lower triglycerides and to reduce the risk of cardiovascular events in patients who have high triglycerides (150 mg/dL or higher). In 2020, annual sales of Vascepa in the United States were over \$600 million.

3. On July 26, 2016, three generic drug manufacturers filed applications with the FDA to launch generic versions of Vascepa. The generic manufacturers, Roxane Laboratories, Inc. and related entities, later acquired by Hikma Pharmaceuticals plc (“Hikma”), Dr. Reddy’s Laboratories Inc. (“DRL”), and Teva Pharmaceuticals USA, Inc. and related entities (“Teva”),¹ contended that all of the asserted patent claims made by Amarin were either invalid or not infringed by their applications for generic versions of Vascepa. Amarin brought suit against the three generic manufacturers alleging patent infringement, which delayed the final approval and launch of generic Vascepa. Another application for generic Vascepa, which was amended in May 2020, was filed by Apotex, Inc. (“Apotex”). Apotex contended that some of the asserted patent claims were either invalid or not infringed by Apotex’s generic version of Vascepa, but did not challenge all of

¹ Applications were previously filed with the FDA, but they were rejected after Amarin successfully extended its New Chemical Entity exclusivity period, rendering those earlier-filed applications premature.

the asserted patent claims.

4. Amarin settled its litigation against Teva in May 2018 and Apotex in June 2020. Pursuant to those settlements, Teva and Apotex agreed to refrain from selling generic versions of Vascepa in the United States until August 9, 2029, or earlier under certain circumstances.

5. Hikma and DRL, however, continued their patent fight and won at trial, with the Court ruling that Amarin's patents were invalid due to obviousness.

6. DRL promptly began preparations to launch generic Vascepa, "only to discover that Amarin had foreclosed all the suppliers of the icosapent ethyl API who have sufficient capacity to support a commercial launch in a timely manner."²

7. Hikma received FDA approval to launch its generic version of 1mg Vascepa on May 22, 2020.³

8. DRL received FDA approval to launch its generic version of 1mg Vascepa on August 7, 2020.⁴ By that point in time, DRL had removed all legal and regulatory barriers to its entry into the market for 1mg Vascepa. However, DRL found itself foreclosed from entering the market due to Amarin's use of exclusive contracts which locked up the world's supply of IPE, the active pharmaceutical ingredient in Vascepa. Through these exclusive contacts with the world's suppliers of IPE, Amarin had a supply that was several times more than it needed based on its anticipated sales.

² Complaint, Doc. No. 1, *Dr. Reddy's Laboratories Inc. v. Amarin Pharma, Inc., Amarin Pharmaceuticals Ireland Limited, and Amarin Corporation PLC*, No. 3:21-cv-10309-BRM-ZNQ (D.N.J. Apr. 27, 2021) ("DRL Complaint"), ¶ 3.

³ "Hikma receives FDA approval for its generic Vascepa," PR Newswire (May 22, 2020), <https://www.prnewswire.com/news-releases/hikma-receives-fda-approval-for-its-generic-vascepa-301064061.html>

⁴ Product Details for ANDA 209499, https://www.accessdata.fda.gov/scripts/cder/ob/results_product.cfm?Appl_Type=A&Appl_No=209499#312

9. Amarin lost its appeal of the District Court's patent invalidity order on September 3, 2020.

10. Hikma launched a very limited amount of its 1mg generic Vascepa on November 5, 2020, as a result of Amarin's anticompetitive supply agreements with the world's main suppliers of IPE. Similarly, due to a lack of IPE, DRL was unable to launch its generic Vascepa product until June 22, 2021.

11. Through the use of sham patent litigation, Amarin was able to delay and limit Hikma and DRL's launches of generic Vascepa (as well as to prevent the approval and/or launches of other generic manufacturers). Further, by purposely contracting with at least four different Active Pharmaceutical Ingredient ("API") suppliers⁵ – one or two is standard in the pharmaceutical industry – Amarin prevented these suppliers from selling IPE to any other generic manufacturer.⁶

12. Amarin prevented, delayed, and limited generic competition in the marketing and sale of Vascepa. There was no legitimate procompetitive reason for Amarin to pursue its sham patent litigation or for entering into exclusive supply agreements with the four IPE suppliers.

13. The total annual capacity of the four suppliers for IPE was more than triple Amarin's requirements at relevant times in the past and is at least double Amarin's current needs. Amarin has touted these exclusive contracts to investors, referring sometimes to "taking advantage of manufacturing barriers to entry,"⁷ but also stating that contracting with a new supplier of IPE "fortifies Amarin's efforts to shield its Vascepa patent beyond its scheduled 2030 expiration."⁸

⁵ Nisshin Pharma Inc., Equatez Ltd., Chemport Inc., and Novasep.

⁶ See, e.g., Amarin Corp. plc, Quarterly Report (Form 10-Q), at 16 (Nov. 8, 2011) ("Following FDA approval of [Vascepa] both agreements [with Equateq and Chemport] include annual purchase levels enabling Amarin to *maintain supply exclusivity* with each respective supplier") (emphasis added).

⁷ Amarin Corp. plc, Annual Report (Form 10-K), at 3 (Feb. 29, 2012).

⁸ Press Release, Amarin Corp. plc, "Amarin Announces Approval of Supplemental New Drug Application for Chemport as Additional Vascepa® Active Pharmaceutical Ingredient Supplier"

14. As a result of Amarin's illegal actions, Hikma's launch of generic Vascepa has been constrained by limited supply and DRL's launch of generic Vascepa was delayed until June 22, 2021. Plaintiff and members of the classes have suffered damages as a result of purchasing Vascepa at prices higher than they otherwise would have been if generic manufacturers had been able to bring their drugs to market.

JURISDICTION AND VENUE

15. This action arises under Sections 1 and 2 of the Sherman Act, (15 U.S.C. §§ 1 and 2) and Section 16 of the Clayton Act (15 U.S.C. § 26), as well as various State antitrust and consumer protection laws. This Court has jurisdiction under 28 U.S.C. §§ 1331 and 1337, as well as Section 16 of the Clayton Act (15 U.S.C. § 26). Additionally, this Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332(d) in that this is a class action involving common questions of law or fact in which the aggregate amount in controversy exceeds \$5,000,000, exclusive of interest and costs; there are more than one hundred members of each class; and at least one member of each of the putative classes is a citizen of a state different from that of one of the Defendants.

16. Further, this Court also has supplemental jurisdiction over state law claims pursuant to 28 U.S.C. § 1367(a).

17. Venue is appropriate within this District under Sections 12 and 16 of the Clayton Act (15 U.S.C. §§ 12 and 16) and 28 U.S.C. §§ 1391(b), (c) and (d). Defendants transact business within this District and/or have agents in and/or that can be found in this District, and a portion of the affected interstate trade and commerce discussed below was carried out in this District. At all relevant times, Amarin's U.S. operations were headquartered in this District.

18. The Court has personal jurisdiction over each of the Defendants. Defendants

(Apr. 18, 2013), <https://investor.amarincorp.com/news-releases/news-release-details/amarin-announces-approval-supplemental-new-drug-application>

have transacted business, maintained substantial contacts, and/or committed overt acts in furtherance of the illegal scheme throughout the United States, including in this District. The scheme has been directed at and has had the intended effect of causing injury to individuals and companies residing in or doing business throughout the United States, including in this District. personal jurisdiction lies under FED. R. CIV. P. 4(k)(2) over the foreign domiciliary defendants.

THE PARTIES

A. Plaintiff

19. Plaintiff Board of Trustees of Heavy and General Laborers of Local Unions 472 and 172 of NJ Welfare Fund is headquartered, with its principal place of business, in Newark, New Jersey. Plaintiff is a joint labor-management sponsored trust fund authorized by Sections 302(c)(5) and (8) of the Labor Relations Management Act (“LMRA”) that was established to provide health and welfare benefits to employees and their families, commonly known as a Taft-Hartley Fund. Plaintiff is also an authorized employee welfare benefit fund within the meaning of Section 3(1) of the Employee Retirement Income Security Act (“ERISA”) to provide a program of health, welfare, legal, and related benefits for its participants and beneficiaries.

20. In at least New Jersey, Plaintiff purchased and/or provided reimbursement for some or all of the purchase price for Vascepa, other than for re-sale, at supra-competitive prices during the Class Period and has thereby been injured in its business and property. In addition, there is a substantial likelihood that Plaintiff will in the future purchase and/or provide reimbursement for Vascepa manufactured by Amarin, and it has purchased and/or intends to purchase and/or provide reimbursement for generic versions of Vascepa, other than for re-sale, once they become available. Plaintiff paid and reimbursed more for these products than it would have absent Defendants’ anticompetitive conduct which resulted in the fixing, raising, maintenance, and stabilization of

prices for Vascepa.

B. Defendants

21. Defendant Amarin Pharma, Inc. is a company organized and existing under the laws of Delaware with its principal place of business at 1430 Route 206, Bedminster, NJ 07921.

22. Defendant Amarin Pharmaceuticals Ireland Limited is a company incorporated under the laws of Ireland with registered offices at 88 Harcourt Street, Dublin 2, Dublin, Ireland.

23. Defendant Amarin Corporation plc is a company incorporated under the laws of England and Wales with principal executive offices at 77 Sir John Rogerson's Quay, Block C, Gran Canal Docklands, Dublin 2, Ireland. Defendants Amarin Pharma, Inc., Amarin Pharmaceuticals Ireland Limited, and Amarin Corporation plc are collectively referred to herein as "Amarin" or "Defendant." Co-Conspirators, various other entities and individuals not named as Defendants in this Complaint, have participated as co-conspirators in the acts complained of and performed acts and made statements which aided and abetted and were in furtherance of the acts alleged herein. Among those co-conspirators were the following:

24. BASF Americas Corporation is a company organized and existing under the laws of Delaware with its principal place of business at 1105 North Market Street, Suite 1306, P.O. Box 8985, Wilmington, DE 19899.

25. BASF Corporation is a company organized and existing under the laws of Delaware with its principal place of business at 100 Park Avenue, Florham Park, NJ 07932.

26. BASF Pharma (Callanish) Limited is a company incorporated under the laws of England with registered offices at 2 Stockport Exchange, Railway Road, Stockport, SK1 3GG, United Kingdom.

27. BASF USA Holding LLC is a company organized and existing under the laws of

Delaware with its principal place of business at 100 Park Avenue, Florham Park, NJ 07932. Defendants BASF Americas Corporation, BASF Corporation, BASF Pharma (Callanish) Limited, and BASF USA Holding LLC are collectively referred to herein as “BASF.”

28. Chemport Inc. is a company incorporated under the laws of the Republic of Korea with its principal place of business at 15-1, Dongsu-dong, Naju-si, Jeollanam-do 520- 330, Korea.

29. Nisshin Pharma, Inc. is a company incorporated under the laws of Japan with its principal place of business at 25, Kanda-Nishiki-cho 1- chome, Chiyoda-ku, Tokyo 101- 8441, Japan.

30. Novasep, LLC is a company organized and existing under the laws of New Jersey with its principal place of business at 23 Creek Circle, Boothwyn, PA 19061.

31. Novasep, Inc. is a company organized and existing under the laws of New Jersey with its principal place of business at 23 Creek Circle, Boothwyn, PA 19061.

32. Groupe Novasep SAS is a company incorporated under the laws of France with its principal place of business at 39, Rue Saint Jean De Dieu Lyon, 69007 France.

33. Finorga SAS is a company organized and existing under the laws of France with its principal place of business at Route De Givors Chasse Sur Rhone, 38670 France. Defendants Novasep, LLC, Novasep, Inc., Group Novasep SAS, and Finorga SAS are collectively referred to herein as “Novasep.”

OBTAINING AND ENFORCING PATENT PROTECTION

34. The Patent Act, 35 U.S.C. § 101, provides that “[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.” To be patentable, subject matter must be novel, non-obvious, and particularly described,

among other things.

A. Patent applicants must provide full and complete information to the PTO when seeking approval of a patent application.

35. The process by which a patent applicant seeks a patent consists of a series of communications between the applicant and the U.S. Patent and Trademark Office (“PTO”) examiner to whom the application is assigned. Other interested parties, such as scientists who have published closely related work or competitors that are pursuing similar products, are generally not allowed to participate in this dialogue.

36. It is the responsibility of the applicant, or their attorney or agent, to accurately explain the invention to the examiner, identify misunderstandings or errors made by the examiner, submit all relevant material and information known to the applicant, and fully and accurately explain the relevance of that material and information to the examiner. Accordingly, applicants (and their representatives) are operating under a duty of candor and good faith in their dealings with the PTO.

37. The duty of candor and good faith is designed to provide the PTO with the information necessary for effective and efficient decision-making. Examiners and other PTO personnel place great reliance on applicants and inventors to fulfill their duty of candor and good faith.

38. The Manual of Patent Examining Procedure reminds attorneys that submission of misleading or inaccurate statements may render the resulting patents unenforceable: “The submission by an applicant of misleading or inaccurate statements of facts during the prosecution of applications for patents has resulted in the patents issuing on such applications being held unenforceable.”

B. The “presumption of validity” for patents is not a conclusive determination.

39. Once issued, patents are generally presumed to be valid. However, the presumption of validity associated with an issued patent is not a conclusive determination that the patent is, in fact, valid. Rather, the presumption of validity is simply a procedural device that allows reviewing bodies to assign the appropriate burdens in proceedings challenging the validity of an issued patent.

40. Patents can be invalidated or held unenforceable, either upon re-examination by the PTO, through a review by the Patent Trial and Appeal Board (“PTAB”), or by a court decision or jury verdict. A patent can be invalidated for a variety of reasons, including lack of novelty, obviousness, indefiniteness, enablement, or fraud or inequitable conduct.

C. “Obvious” inventions are not patentable.

41. One reason why a claimed invention may be denied a patent, or why an issued patent may later be invalidated, is a determination that the invention was “obvious.”

42. A patent claim is invalid as obvious if the purported differences between the subject matter sought to be patented and the prior art are such that the subject had been obvious to a person of ordinary skill in the art. If the prior art and the general knowledge of a person of ordinary skill in the art would be sufficient to teach all parts of the claim, the patent claim is obvious and generally cannot be allowed.

43. The question of obviousness is resolved through underlying factual determinations including: (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of ordinary skill in that art; and (4) “secondary” evidence of non-obviousness.

44. A patent applicant can attempt to overcome an obviousness rejection by pointing to “secondary considerations,” also referred to as objective indicia of obviousness, such as the

commercial success of the claimed invention, a long-felt but unsolved need for the claimed invention, and the failure of others in attempting to make the claimed invention.

D. Patent Challenges

45. To address the fact that invalid patents can sometimes gain approval, patents are challengeable in court.

46. In the case of pharmaceutical patents, a generic drug manufacturer can prevail in patent infringement litigation by showing that its product does not infringe the patent (and/or that the patent holder cannot meet its burden to prove infringement). It may also, or in the alternative, show that the patent itself is invalid or unenforceable. For example, a patent is invalid or unenforceable when the disclosed invention is obvious in light of prior art.

47. In those circumstances, the PTO's decision to issue a patent does not substitute for a fact-specific assessment of (i) whether the applicant made intentional misrepresentations or omissions on which the PTO relied in issuing the patent, and (ii) whether a reasonable manufacturer in the patent holder's position would have a realistic likelihood of succeeding on the merits of a patent infringement suit.

48. The Federal Trade Commission ("FTC") reported that generics prevailed in 73% of Hatch-Waxman patent litigation cases resolved on the merits between 1992 and 2002. An empirical study of all substantive decisions rendered in every patent case filed in 2008 and 2009 similarly reported that when a generic challenger litigated until a decision on the merits, the generic won 74% of the time.

REGULATORY BACKGROUND

A. Approval of a first entrant

49. Under the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §

301 et seq., manufacturers that create a new drug must obtain approval from the FDA to sell the product by filing a New Drug Application (“NDA”).⁹ An NDA must include specific data concerning the safety and effectiveness of the drug, as well as any information on applicable patents.¹⁰

50. When the FDA approves a brand pharmaceutical manufacturer’s NDA, the manufacturer may list in *Approved Drug Products with TherapeuticEquivalence Evaluations* (the “Orange Book”) certain patents that the manufacturer asserts could reasonably be enforced against a manufacturer that makes, uses, or sells a generic version of the brand drug before the expiration of the listed patents. After the FDA approves the NDA, the brand manufacturer may list such patents in the Orange Book.¹¹

51. When they do not face generic competition, brand manufacturers can usually sell the brand drug far above the marginal cost of production, generating profit margins well in excess of 70%, while making hundreds of millions of dollars in sales.

B. Approval of a generic drug

52. Once lawful periods of patent exclusivity expire on brand drug products, generic drug manufacturers can seek FDA approval to market and sell generic versions of the brand drug. Under the Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984)—commonly known as “Hatch-Waxman”—competitors wishing to sell a generic equivalent of a brand drug may file an abbreviated new drug application (“ANDA”), which relies in substantial part on the scientific findings of safety and efficacy contained in the brand drug manufacturer’s NDA.

⁹ 21 U.S.C. §§ 301-392.

¹⁰ 21 U.S.C. §§ 355(a), (b).

¹¹ 21 U.S.C. §§ 355(b)(1), (c)(2).

53. To gain FDA approval, generic drugs must be bioequivalent to their brand counterparts. Bioequivalence means that the active ingredient of the proposed generic would be present in the blood of a patient to the same extent and for the same amount of time as the active ingredient of the brand.¹² Bioequivalent drug products containing identical amounts of the same active ingredients, having the same route of administration and dosage form, and meeting applicable standards of strength, quality, purity, and identity are therapeutically equivalent and may be substituted for one another.

54. Because generic drugs are therapeutically equivalent to brand-name drugs, generic manufacturers compete by offering their drugs at low prices. Entry of a single generic can result in steep price reductions for purchasers. Entry of several generics tends to result in even steeper price reductions, driving price down close to marginal manufacturing costs.

55. To benefit from these low prices, every state has adopted substitution laws requiring or permitting pharmacies to substitute generic equivalents when filling brand drug prescriptions, unless the prescribing physician specifically directs otherwise. Due in part to these substitution laws, the launch of bioequivalent generics causes a rapid price decline and shift from brand to generic drug sales. A generic that is unconstrained by supply issues often captures 80% or more of the market within the first six months of entry. The effects of generic entry are still more dramatic after a year. In a review of industry data, the FTC found that on average, within a year of generic entry, generics had captured 90% of corresponding brand sales and prices had dropped 85% when there were multiple generics on the market.¹³

¹² 21 U.S.C. § 355(j)(8)(B).

¹³ See Federal Trade Commission, Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions 8 (2010), <https://www.ftc.gov/sites/default/files/documents/reports/pay-delay-how-drug-company-payoffs-cost-consumers-billions-federal-trade-commission-staff-study/100112payfordelayrpt.pdf>.

C. Regulatory exclusivities

56. A “new chemical entity” is a drug that contains an active moiety—the part of the drug responsible for the physiological or pharmacological action of the drug—that the FDA has not previously approved in another NDA.¹⁴ Approval of an ANDA with a new chemical entity provides a five-year exclusivity (“NCE exclusivity”) during which the FDA cannot approve an ANDA for a drug containing the same active moiety as the new chemical entity.¹⁵

D. ANDA Paragraph IV Certifications

57. To obtain FDA approval of an ANDA, a manufacturer must certify that the generic drug will not infringe any patents listed in the Orange Book. Under the Hatch-Waxman Amendments, a generic manufacturer’s ANDA must contain one of four certifications:

- i. that no patent for the brand drug has been filed with the FDA (a “Paragraph I certification”);
- ii. that the patent for the brand drug has expired (a “Paragraph II certification”);
- iii. that the patent for the brand drug will expire on a particular date and the manufacturer does not seek to market its generic product before that date (a “Paragraph III certification”); or
- iv. that the patent for the brand drug is invalid or will not be infringed by the generic manufacturer’s proposed product (a “Paragraph IV certification”).

21 U.S.C. § 355(j)(2)(A)(vii).

58. If a generic manufacturer files a Paragraph IV certification, a brand manufacturer can delay FDA approval of the ANDA simply by suing the ANDA applicant for patent infringement. If the brand manufacturer initiates a patent infringement action against the generic filer within forty-five days of receiving notification of the Paragraph IV certification, the FDA

¹⁴ 21 C.F.R. § 314.108(a).

¹⁵ 21 C.F.R. § 314.108(b)(2).

will not grant final approval to the ANDA until the earlier of (a) the passage of 30 months, or (b) the issuance of a decision by a court that the patent is invalid or not infringed by the generic manufacturer's ANDA. 21 U.S.C. § 355(j)(5)(B)(iii).¹⁶

59. Until one of those conditions occurs, the FDA may grant “tentative approval,” but cannot authorize the generic manufacturer to market its product (*i.e.*, grant final approval). The FDA may grant an ANDA tentative approval when it determines that the ANDA would otherwise be ready for final approval but for the 30-month stay.

E. The First Filer's 180-day Exclusivity Period

60. Generics may be classified as (i) first filer generics, (ii) later generic filers, and (iii) authorized generics.

61. To encourage manufacturers to seek approval of generic versions of brand drugs, the Hatch-Waxman Amendments grant the first Paragraph IV generic manufacturer ANDA filer (“first filer”) a 180-day exclusivity period to market the generic version of the drug, during which the FDA may not grant final approval to any other generic manufacturer's ANDA for the same brand-name drug. *See* 21 U.S.C. §§ 355(j)(5)(B)(iv), 355(j)(5)(D). That is, when a first filer files a substantially complete ANDA with the FDA and certifies that the unexpired patents listed in the Orange Book as covering the brand product are either invalid or not infringed by the generic product, the FDA cannot approve a later generic company's ANDA until that first generic has been on the market for 180 days, or until its first-filer exclusivity has been forfeited.

62. The Supreme Court has recognized that “this 180-day period of exclusivity can

¹⁶ This period is commonly called a “30-month stay.” The brand/patent holder can choose to sue the generic after 45 days, including waiting until the generic has launched its product, but, in that event, the brand cannot take advantage of the 30-month stay of FDA approval, and must instead satisfy the showing required to obtain a preliminary injunction to prevent the generic launch.

prove valuable, possibly ‘worth several hundred million dollars’” to the first filer.¹⁷

63. A first filer that informs the FDA that it intends to wait until all Orange Book listed patents expire before marketing its generic does not get a 180-day exclusivity period. Congress created this 180-day period to incentivize generic manufacturers to challenge weak or invalid patents, or to invent around such patents by creating non-infringing generics.

F. Supply and Use of API in Drug Products

64. Final drug products consumed by patients and the active pharmaceutical ingredients contained in those final drug products are frequently manufactured by different companies. In such cases the manufacturer of the final drug product, whether brand or generic, combines the API purchased from other sources with inactive ingredients to manufacture the final dosage form. Although a generic manufacturer’s process for manufacturing the final dosage form may be different from the manufacturer of the Reference Listed Drug (“RLD”), it is typical for the different manufacturers to use identical API.

65. As part of the process for obtaining regulatory approval to sell an active pharmaceutical ingredient in the United States, the API manufacturer ordinarily must file a Drug Master File (“DMF”) with the FDA. The DMF provides “confidential detailed information about facilities, processes, or articles used in the manufacturing, processing, packaging, and storing of” the API.¹⁸ The manufacturer of a final dosage form, in turn, references the DMF of each of its API suppliers in its New Drug Application (whether Abbreviated or full).¹⁹ The FDA then reviews the technical information contained therein, and inspects the relevant facilities described

¹⁷ *FTC v. Actavis, Inc.*, 133 S. Ct. 2223, 2229 (2013) (quoting C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. Rev. 1553, 1579 (2006)).

¹⁸ Guidelines For Master Drug Files, § I, <https://www.fda.gov/drugs/guidances-drugs/drug-master-files-guidelines>

¹⁹ 21 CFR § 314.420(b).

therein, of each DMF referenced in the ANDA or NDA. A single DMF may be referenced by multiple manufacturers.

66. It takes significant time to develop a process for manufacturing an API and then prepare and file the necessary DMF.

67. If a manufacturer wants or needs to change its API supplier for a drug, it must file a supplement with the FDA referencing the new API supplier's DMF and submit data for drug batches using the new supplier's API. The manufacturer may only market its drug using the new supplier's API if the FDA approves of the change. It is time consuming to prepare and file the necessary supplement and then obtain FDA approval of the change in API supplier.

68. If a current DMF holder is willing, a generic manufacturer may use API from an API supplier that already has a DMF on file and reference that DMF in their ANDAs. If, however, no current DMF holder is willing to supply the generic manufacturer with API, it must identify a new API supplier (who does not yet have a DMF on file) and work with that supplier to develop the API and submit a DMF.

69. Generally, because of the significant costs involved in qualifying an API supplier, as well as the need to continue to ensure quality control by the API supplier, it is industry practice for both brand and generic drug manufacturers to use only one or two API suppliers to support a drug application.²⁰

ECONOMIC BACKGROUND

70. The marketplace for the sale of prescription pharmaceutical products in the United States is distinctive. In most industries, the person who pays for a product is also the person who

²⁰ See, e.g., Mallu UR, Nair AK, Bapatu HR, Pavan Kumar M, Narla S, et al., "API Supplier Change or Addition of Alternate API Supplier in Generic Drug Products: Cost, Quality and Regulatory Factors" (Pharmaceutical Analytica Acta 2015) at 2 ("[T]wo suppliers shall be selected one as main and another one as alternative supplier for generic DP development.").

chooses the product. When the same person has both the payment obligation and the choice of products, the price of the product plays a predominant role in the choice of products. Consequently, manufacturers have a strong incentive to lower the price of their products to maintain profitability.

71. The pharmaceutical marketplace, in contrast, is characterized by a “disconnect” between the payment obligation and the product selection. State laws prohibit pharmacists from dispensing certain drugs to patients unless they can present a prescription written by their physician. This prohibition introduces an anomaly into the pharmaceutical marketplace between the payment obligation and the product selection. The patient (and in many cases his or her insurer) has the obligation to pay for the pharmaceutical product, but his or her doctor chooses which product the patient will buy.

72. In 1984, Congress sought to ameliorate the “disconnect” by authorizing the manufacture and sale of generic pharmaceuticals under the Hatch-Waxman Amendments. Since the passage of the Hatch-Waxman Amendments, every state has adopted drug product selection laws that either require or permit pharmacies to substitute AB-rated generic equivalents for brand prescriptions (unless the prescribing physician specifically directs that substitution is not permitted). In this way, price reenters the product selection decision at the pharmacy counter, lessening the pharmaceutical marketplace “disconnect.” When a therapeutically equivalent generic is introduced and not prevented from competing, brand manufacturers can no longer exploit the “disconnect,” their monopoly power dissipates, and some of the normal competitive pressures are restored.

73. Because generic versions of brand drugs contain the same active ingredients and are determined by the FDA to be just as safe and effective as their brand counterparts, the only

material differences between generic drugs and their brand counterparts are their prices and manufacturers. Because generic versions of brand products are commodities that cannot be differentiated, the primary basis for generic competition is price.

74. Typically, generics are at least 25% less expensive than their brand counterparts when there is a single generic competitor. They are 50% to 80% (or more) less expensive when there are multiple generic competitors on the market for a given brand. Consequently, the launch of a bioequivalent generic drug usually results in significant cost savings to all drug purchasers.

75. Once a generic hits the market, it quickly captures sales of the corresponding brand drug, often 80% or more of the market, within the first six months after entry. In one study, the FTC found that on average, within a year of generic entry, generics had captured 90% of corresponding brand sales and, with multiple generics on the market, prices had dropped 85%. As a result, competition from generics is viewed by brand manufacturers, such as Amarin, as a grave threat to their bottom lines.

76. Until the generic version of a brand drug enters the market, there is no bioequivalent generic to substitute for, and thus compete with, the brand drug, so the brand drug manufacturer can continue to profitably charge supra-competitive prices. As a result, brand drug manufacturers, well aware of the rapid erosion of brand drug sales by generic drugs, have a strong incentive to delay the start of generic drug competition into the market. Brand manufacturers often seek to extend their monopolies, sometimes resorting to illegal ones, including fraud on the PTO and subsequent sham litigation against generics seeking to enter the market.

77. The Hatch-Waxman Amendments have significantly advanced the rate of generic drug launches while also ushering in an era of historically high profits for brand drug manufacturers. In 1983, before the Hatch-Waxman Amendments, only 35% of the top-selling

brand drugs with expired patents had generic alternatives; by 1998, nearly all did. In 1984, annual prescription drug revenue for brand and generic drugs totaled \$21.6 billion; by 2013, total annual prescription drug revenue had soared to \$329.2 billion.

FACTS

A. Vascepa

78. Vascepa is a highly purified preparation of EPA (eicosapentaenoic acid), also known as icosapent ethyl, which was first approved by the FDA in July 2012 as “an adjunct to diet to reduce triglyceride (“TG”) levels in adult patients with severe [] hypertriglyceridemia.” Subsequently, the FDA determined that Vascepa was entitled to NCE exclusivity, which ran from the NDA approval date to July 26, 2017.

79. Vascepa aims to beneficially lower the levels of certain fats, or lipids, in the bloodstream using purified omega-3 fatty acids from fish oil. Two types of lipids are triglycerides (“TGs”) and cholesterol.

80. TGs are a major source of energy in the human diet. After TGs are absorbed from the intestine, they are broken down into component molecules, resynthesized, and reassembled by the intestine into lipoproteins. The major proteins in lipoproteins are called apolipoproteins – Apo B being one type.

81. Cholesterol levels measured in the blood are generally an indicator for the amount of low-density lipoprotein cholesterol (“LDL-C”). LDL-C is the “bad cholesterol” that physicians and patients often try to reduce with drugs such as statins.

82. The patents for Vascepa (discussed below) largely concern methods of treating severe hypertriglyceridemia (“HTG”), which refers to very high levels of TGs in the blood. HTG means a patient that has triglycerides levels greater than or equal to 500 milligrams per deciliter.

83. For patients with elevated levels of TGs, the primary therapy goal is to maintain target levels of LDL-C, because elevated LDL-C can be a cause of coronary heart disease. Patients with HTG, however, have an elevated risk of acute pancreatitis (an inflammation of the pancreas, which can be life-threatening), and so the aim of therapy is to lower TG levels.

84. The patents for Vascepa concern methods of treating HTG by administering 4 grams of purified EPA (eicosapentaenoic acid) per day, which reduces TGs without increasing LDL-C.

85. On December 13, 2019, the FDA approved a new indication for Vascepa: “as an adjunct to maximally tolerated statin therapy to reduce the risk of myocardial infarction, stroke, coronary revascularization, and unstable angina requiring hospitalization in adult patients with elevated triglyceride (TG) levels (≥ 150 mg/dL) and . . . established cardiovascular disease or . . . diabetes mellitus and 2 or more additional risk factors for cardiovascular disease.” The new indication is entitled to data exclusivity, which is scheduled to expire on December 13, 2022.

86. Amarin currently markets Vascepa in the 1g and 500mg strengths. Amarin has raised the price of 1g Vascepa dramatically since its launch: the list price for the 1mg strength of Vascepa was estimated to be \$308.25 per month in 2019,²¹ \$355 per month in 2020,²² and is currently estimated to be around \$368.86.²³

87. Vascepa is Amarin’s only product, with revenues of \$607 million in 2020.²⁴

²¹ “J&J’s Xarelto, Amarin’s Vascepa are cost-effective, not budget friendly,” EndpointsNews (Oct. 18, 2019), <https://endpts.com/jjs-xarelto-amarins-vascepa-are-cost-effective-but-not-budget-friendly-icer/>.

²² “A cardiologist asks: How much is too much to pay for a promising drug?,” The Philadelphia Inquirer (Jan. 20, 2020), <https://www.inquirer.com/health/expert-opinions/vascepa-price-cardiology-triglycerides-fish-oil-20200122.html>.

²³ “Vascepa Prices, Coupons, and Patient Assistant Programs,” <https://www.drugs.com/price-guide/vascepa>.

²⁴ Amarin Corp. plc, Annual Report (Form 10-K), at F-5 (Feb. 25, 2021).

B. Amarin Lists Numerous Invalid Patents for Vascepa which are Later Challenged by Generic Manufacturers

88. Six patents that were listed for Vascepa in the Orange Book were at issue at trial in the Vascepa Patent Litigation, as described below. These patents, all entitled “METHODS OF TREATING HYPERTRIGLYCERIDEMIA,” included: U.S. Patent No. 8,293,728 (the “’728 Patent”), U.S. Patent No. 8,318,715 (the “’715 Patent”), U.S. Patent No. 8,357,677 (the “’677 Patent”), U.S. Patent No. 8,367,652 (the “’652 Patent”), U.S. Patent No. 8,431,560 (the “’560 Patent”) and U.S. Patent No. 8,518,929 (the “’929 Patent”).

The ’728 Patent

89. The ’728 Patent issued on October 23, 2012, from Application No. 13/349,153, to Mehar Manku, Ian Osterloh, Pierre Wicker, Rene Braeckman, and Paresh Soni (the “Inventors”). According to the Orange Book, the ’728 Patent expires on February 9, 2030. Claims 1 and 16 of the ’728 Patent were at issue in the Vascepa Patent Litigation.

1. A method of reducing triglycerides in a subject having a fasting baseline triglyceride level of 500 mg/dl to about 1500 mg/dl who does not receive concurrent lipid altering therapy comprising: administering orally to the subject about 4 g per day of a pharmaceutical composition comprising at least about 96% by weight of all fatty acids present, ethyl eicosapentaenoate, and substantially no docosahexaenoic acid or its esters for a period of 12 weeks to effect a reduction in triglycerides without substantially increasing LDL-C compared to a second subject having a fasting baseline triglyceride level of 500 mg/dl to about 1500 mg/dl who has not received the pharmaceutical composition and a concurrent lipid altering therapy.
16. The method of claim 1, wherein no fatty acid of the pharmaceutical composition, except for ethyl-EPA, comprises more than about 0.6% by weight of all fatty acids combined.

The ’715 Patent

90. The ’715 Patent issued to the Inventors on November 27, 2012, from Application

No. 13/282,145. According to the Orange Book, the '715 Patent expires on February 9, 2030.

Claim 14 of the '715 Patent was at issue in the Vascepa Patent Litigation.

13. A method of reducing triglycerides in a subject having a fasting baseline triglyceride level of 500 mg/dl to about 1500 mg/dl, who does not receive concurrent lipid altering therapy, comprising administering orally to the subject about 4 g per day of a pharmaceutical composition comprising at least about 96% by weight, ethyl eicosapentaenoate (ethyl-EPA) and substantially nodocosahexaenoic acid (DHA) or its esters for a period of at least 12 weeks to effect a statistically significant reduction in triglycerides without effecting a statistically significant increase in LDLC or apolipoprotein B in the subject.
14. The method of claim 13 comprising administering to the subject about 4 g per day of the pharmaceutical composition to effect a statistically significant reduction in triglycerides and apolipoprotein B without effecting a statistically significant increase of LDL-C in the subject.

The '677 Patent

91. The '677 Patent issued to the Inventors on January 22, 2013, from Application No. 13/608,775. According to the Orange Book, the '677 Patent expires on February 9, 2030. Claims 1 and 8 of the '677 Patent were at issue in the Vascepa Patent Litigation.

1. A method of reducing triglycerides in a subject having a fasting baseline triglyceride level of 500 mg/dl to about 1500 mg/dl comprising: administering orally to the subject about 4 g per day of a pharmaceutical composition comprising at least about 96% by weight of all fatty acids present, ethyl eicosapentaenoate and substantially no docosahexaenoic acid or its esters for a period of at least about 12 weeks to effect a reduction in triglycerides without substantially increasing LDL-C compared to placebo control.
8. The method of claim 1, comprising administering to the subject about 4 g of the pharmaceutical composition daily for the period of at least about 12 weeks to effect a reduction in apolipoprotein B compared to placebo control.

The '652 Patent

92. The '652 Patent issued to the Inventors on February 5, 2013, from Application No. 13/610,247. According to the Orange Book, the '652 Patent expires on February 9, 2030. Claim 1 of the '652 Patent were at issue in the Vascepa Patent Litigation.

1. A method of reducing triglycerides in a subject having a fasting baseline triglyceride level of 500 mg/dl to about 1500 mg/dl comprising: administering orally to the subject about 4 g per day of a pharmaceutical composition comprising at least about 96% by weight of all fatty acids present, ethyl eicosapentaenoate and substantially no docosahexaenoic acid or its esters for a period of about 12 weeks to effect a reduction in triglycerides without substantially increasing LDL-C compared to baseline.

The '560 Patent

93. The '560 Patent issued to the Inventors on October 23, 2012, from Application No. 13/711,329. According to the Orange Book, the '560 Patent expires on February 9, 2030. Claims 4 and 17 of the '560 Patent were at issue in the Vascepa Patent Litigation.

1. A method of reducing triglycerides in a subject having a fasting baseline triglyceride level of 500 mg/dl to about 1500 mg/dl comprising, administering orally to the subject 4 capsules per day, each capsule comprising about 900 mg to about 1 g of ethyl eicosapentaenoate and not more than about 3% docosahexaenoic acid or its esters, by weight of total fatty acids present, for a period of 12 weeks to effect a reduction in triglycerides in the subject.
4. The method of claim 1, wherein said administering effects a reduction in fasting triglycerides of at least about 10% without increasing the LDL-C by more than 5% in the subject.
11. A method of reducing triglycerides in a subject having a fasting baseline triglyceride level of 500 mg/dl to about 1500 mg/dl comprising, administering orally to the subject 4 capsules per day, each capsule comprising about 900 mg to about 1 g of ethyl eicosapentaenoate and not more than about 3% docosahexaenoic acid or its esters, by weight of total fatty acids present, for a period of 12 weeks to effect a reduction in triglycerides in the subject compared to placebo control.

17. The method of claim 11, wherein said administering effects reduction in fasting triglycerides of at least about 20% without increasing LDL-C in the subject compared to placebo control.

The '929 Patent

94. The '929 Patent issued to the Inventors on August 27, 2013, from Application No. 13/776,242. According to the Orange Book, the '929 Patent expires on April 29, 2030. Claims 1 and 5 of the '929 Patent were at issue in the Vascepa Patent Litigation.

1. A method of reducing triglycerides in a subject having fasting triglycerides of at least 500 mg/dl comprising, orally administering to the subject daily for at least about 12 weeks a pharmaceutical composition comprising about 4 g ethyl eicosapentaenoate and not more than about 4% docosahexaenoic acid or its esters, by weight of all fatty acids.
5. The method of claim 1, wherein 12 weeks of said daily administration is effective to reduce apolipoprotein B in subjects who have fasting triglycerides levels of at least 500 mg/dl.

100. As described by the court in the Vascepa Patent Litigation:

... the [above patents] were initially rejected as obvious, but the patent examiner responsible for reviewing them later issued materially identical statements of allowance permitting the [] Patents to issue because he found [] certain secondary considerations of non obviousness ... He specifically found the pending claims patentable because 'Applicant was able to overcome the above 103 obviousness rejection by showing: 1 – Unexpected results, and 2 – Long felt unmet medical need.'

101. In addition to the above patents, the Orange Book lists for Vascepa, among others, U.S. Patent No. 8,188,146 (the "'146 Patent"), entitled "Highly purified ethyl EPA and other EPA derivatives." The '146 Patent was not at issue in the Vascepa Patent Litigation. According to the Orange Book, the '146 Patent expired on January 27, 2020.

C. Several Generic Manufacturers Seek Regulatory Approval for Generic Vascepa

102. On or about July 26, 2016, three generic manufacturers—Hikma (ANDA No.

209457), DRL (ANDA No. 209499), and Teva (ANDA No. 209525)—submitted ANDAs to the FDA for generic versions of Vascepa.

103. The ANDAs of Hikma, DRL, and Teva included Paragraph IV certifications for the '728 Patent, the '715 Patent, the '677 Patent, the '652 Patent, the '560 Patent and the '929 Patent, among others, alleging that these patents were invalid and/or would not be infringed by their generic product.

104. On September 21, 2016, Hikma notified Amarin of its submission of its ANDA and Paragraph IV certifications. DRL notified Amarin of its ANDA and Paragraph IV certifications by letter on September 22, 2016. And, Teva sent its letter to Amarin concerning its ANDA and Paragraph IV certifications on October 7, 2016.

105. Because Hikma, Teva, and DRL filed their ANDAs on the same day, each was considered a first filer and was eligible for 180-day exclusivity for generic Vascepa (which would be shared).

D. Amarin Delays Generic Entry by Attempting to Enforce its Invalid Patents

106. Amarin sued Hikma for patent infringement on October 31, 2016, in the U.S. District Court for the District of Nevada, *Amarin Pharma, Inc. v. Roxane Laboratories, Inc.*, No. 2:16-cv-02525-MMD-NJK (D. Nev.).

107. Amarin sued DRL for patent infringement on November 4, 2016, in the U.S. District Court for the District of Nevada, *Amarin Pharma, Inc. v. Dr. Reddy's Laboratories, Inc.*, No. 2:16-cv-02562-MMD-NJK (D. Nev.).

108. Amarin sued Teva for patent infringement on November 18, 2016, in the U.S. District Court for the District of Nevada, *Amarin Pharma, Inc. v. Teva Pharmaceuticals USA, Inc.*, No. 2:16-cv-02658-MMD-NJK (D. Nev.).

109. In each of the three cases, Amarin asserted the infringement of 14 patents, including the '728 Patent, the '715 Patent, the '677 Patent, the '652 Patent, the '560 Patent and the '929 Patent.

110. The filing of these lawsuits triggered the Hatch-Waxman 30-month stay as to the approval of the Hikma, DRL, and Teva ANDAs for generic Vascepa.

111. The three cases were consolidated in January of 2017 under the caption *Amarin Pharma, Inc. v. Roxane Laboratories, Inc.*, No. 2:16-cv-02525- MMD-NJK (D. Nev.) (the “Vascepa Patent Litigation”).

112. On May 24, 2018, Amarin announced that it had entered into a settlement agreement with Teva resolving the litigation between the parties. According to a press release issued by Amarin, “[a]s part of the settlement agreement, Teva may first begin selling its generic version of Vascepa in the United States on August 9, 2029, or earlier under certain customary circumstances.”²⁵

113. In the course of the Vascepa Patent Litigation, Amarin dropped its claims with respect to 8 of its originally asserted patents. The case proceeded to a bench trial against Hikma and DRL in January 2020, and the only patents remaining at issue for trial were the '728 Patent, the '715 Patent, the '677 Patent, the '652 Patent, the '560 Patent and the '929 Patent.

114. On March 30, 2020, Judge Miranda M. Du issued a Bench Order invalidating all of Amarin’s asserted patent claims. Judge Du concluded that while Hikma’s and DRL’s ANDAs infringed, all of Amarin’s asserted patent claims were invalid as obvious. Judge Du thus entered judgment for Hikma and DRL.

²⁵ Press Release, Amarin Corp. plc, “Amarin Announces Patent Litigation Settlement Agreement with Teva” (May 24, 2018), <https://investor.amarincorp.com/news-releases/news-release-details/amarin-announces-patent-litigation-settlement-agreement-teva>.

115. On the issue of invalidity, Judge Du found that Hikma and DRL “established by clear and convincing evidence at Trial that all Asserted Claims are *prima facie* obvious. Plaintiffs’ arguments to the contrary are unavailing.”

116. With respect to the secondary considerations of obviousness, Judge Du found that Vascepa’s commercial success weighed in favor of Amarin and that the satisfaction of a long-felt need weighed “slightly” in favor of Amarin, but that the remaining secondary considerations weighed in favor of Hikma and DRL.

117. Judge Du concluded that “at best, Plaintiffs have presented weak evidence of the existence of secondary considerations, which do not overcome the Court’s finding that all Asserted Claims are *prima facie* obvious.”

118. Amarin promptly issued a press release setting forth its disagreement with Judge Du’s decision and describing its “effort to prevent a generic launch” through an appeal and additional litigation.²⁶

119. Amarin appealed Judge Du’s order to the U.S. Court of Appeals for the Federal Circuit. On September 3, 2020, the appellate panel upheld the trial court’s decision, summarily affirming the invalidation of Amarin’s patents the day after oral argument. Then, on November 4, 2020, the court denied Amarin’s motions for rehearing and rehearing *en banc*.

120. After the Federal Circuit panel decision, Amarin issued another press release, stating that “Amarin anticipates that generics companies, when they launch in the United States, are likely to have limited supply capacity for VASCEPA.”²⁷

²⁶ Press Release, Amarin Corp. plc, “Amarin Comments on Ruling in Vascepa ANDA Litigation” (Mar. 30, 2020), <https://investor.amarincorp.com/news-releases/news-release-details/amarin-comments-ruling-vascepar-anda-litigation>.

²⁷ Press Release, Amarin Corp. plc, “Amarin Provides Update Following Ruling in Vascepa ANDA Patent Litigation” (Sept. 3, 2020), <https://investor.amarincorp.com/news-releases/news-release-details/amarin-provides-update-following-ruling-vascepar-anda-patent>.

121. On February 11, 2021, Amarin filed a petition of certiorari with U.S. Supreme Court, however the Supreme Court denied Amarin's petition on June 21, 2021.

122. Absent Amarin's sham litigation and the delay caused thereby, one or more generic versions of Vascepa could have been available no later than January 27, 2020, upon the expiration of the '146 Patent.

E. Amarin set out to lock up the world's supply of Vascepa API for the explicit purpose of preventing generic competition

123. As discussed above, the API for Vascepa is IPE, which is derived from fish oil.

124. For more than a decade, Amarin has set out to lock up the world's supply of IPE for the explicit purpose of "protecting the potential commercial exclusivity" of Vascepa.²⁸

125. From the beginning, Amarin stated its intention to take advantage of manufacturing barriers to entry to prevent competition: "We will seek to protect the potential commercial exclusivity of [Vascepa] through a combination of obtaining and maintaining intellectual property rights and regulatory exclusivity, *taking advantage of manufacturing barriers to entry* and maintaining trade secrets."²⁹

126. On April 18, 2013, Amarin announced that it had filed a supplemental New Drug Application ("sNDA") to add Chemport Inc. ("Chemport") as an API supplier.³⁰ In that announcement, Amarin confirmed that the "manufacturing barriers to entry" that it intended to take advantage of are the various exclusive contracts that it used to foreclose the supply of Vascepa

²⁸ Amarin Corp. plc Annual Report (Form 10-K), at 3 (Feb. 20, 2012).

²⁹ *Id.* (emphasis added); *see also* Amarin Corp. plc Annual Report (Form 10-K), at 21 (Feb. 27, 2014) ("FDA marketing exclusivity is separate from, and in addition to, patent protection, trade secrets and manufacturing barriers to entry which also help protect Vascepa against generic competition.").

³⁰ Press Release, Amarin Corp. plc, "Amarin Announces Approval of Supplemental New Drug Application for Chemport as Additional Vascepa® Active Pharmaceutical Ingredient Supplier" (Apr. 18, 2013), <https://investor.amarincorp.com/news-releases/news-release-details/amarin-announces-approval-supplemental-new-drug-application>.

API: “The addition of Chemport contributes to the planned expansion of the Vascepa manufacturing supply chain and *is additional progress toward Amarin’s goal to protect the commercial potential of Vascepa to beyond 2030 through a combination of patent protection, regulatory exclusivity, trade secrets and by taking advantage of manufacturing barriers to entry.*”³¹

127. Joseph Zakrewski, Amarin’s CEO, further confirmed that the key barrier to entry was the supply of API, stating that: “The move [to add Chemport as an API supplier] *also fortifies Amarin’s efforts to shield its Vascepa patent beyond its scheduled 2030 expiration.*”³²

128. Amarin further explained its anticompetitive strategy in its 2014 Annual Report:

Certain of our agreements with our suppliers include minimum purchase obligations and limited exclusivity provisions based on such minimum purchase obligations. If we do not meet the respective minimum purchase obligations in our supply agreements, our suppliers, in certain cases, will be free to sell the active pharmaceutical ingredient of Vascepa to potential competitors . . .

While we anticipate that intellectual property barriers and FDA regulatory exclusivity will be the primary means to protect the commercial potential of Vascepa, the availability of Vascepa active pharmaceutical ingredient from our suppliers to our potential competitors would make our competitors’ entry into the market easier and more attractive.³³

129. Amarin expected its scheme to work and wanted the market to know that fact: “In April 2012, the FDA published draft guidance for companies that may seek to develop generic versions of Vascepa. If an application for a generic version of Vascepa were filed and if new chemical entity, or NCE exclusivity is not granted to Vascepa, the FDA may accept the filing for

³¹ *Id.* (emphasis added).

³² “Amarin wins U.S. nod to add S. Korea supplier,” Hartford Business Journal (Apr. 19, 2013) (emphasis added), <https://www.hartfordbusiness.com/article/amarin-wins-us-nod-to-add-s-korea-supplier>

³³ Amarin Corp. plc, Annual Report (Form 10-K), at 40 (Mar. 3, 2015).

review, and we would likely engage in costly litigation with the applicant to protect our patent rights. If the generic filer is ultimately successful in patent litigation against us, meets the requirements for a generic version of Vascepa to the satisfaction of the FDA (after any applicable regulatory exclusivity period and, typically, the litigation-related 30-month stay period expires), ***and is able to supply the product in significant commercial quantities***, the generic company could, with the market introduction of a generic version of Vascepa, limit our U.S. sales, which would have an adverse impact on our business and results of operations.”³⁴

130. Amarin further warned the market that failure of its anticompetitive scheme was a material investment risk: “Risks Related to our Reliance on Third Parties – We may not be able to maintain our exclusivity with our third-party Vascepa suppliers if we do not meet minimum purchase obligations due to lower than anticipated sales of Vascepa.”³⁵

F. Amarin has, in fact, locked up the world’s supply of Vascepa API

131. To effectuate its anticompetitive scheme, Amarin has entered into exclusive or *de facto* exclusive agreements with at least four of the largest suppliers for icosapent ethyl API, and has otherwise secured exclusive supply from yet another supplier.

132. In February 2009 Amarin entered into a supply agreement with Japan-based Nisshin

³⁴ Amarin Corp. plc, Quarterly Report (Form 10-Q), at 31 (Aug. 8, 2013) (emphasis added).

³⁵ Amarin Corp. plc, Quarterly Report (Form 10-Q), at 46 (Nov. 7, 2013); *see also* Amarin Corp. plc, Quarterly Report (Form 10-Q), at 59 (Aug. 7, 2014) (“Certain of our agreements with our suppliers include minimum purchase obligations and limited exclusivity provisions based on such minimum purchase obligations. If we do not meet the respective minimum purchase obligations in our supply agreements, our suppliers, in certain cases, will be free to sell the active pharmaceutical ingredient of Vascepa to potential competitors of Vascepa. Similarly, if we terminate certain of our supply agreements, such suppliers may be free to sell the active pharmaceutical ingredient of Vascepa to potential competitors of Vascepa. While we anticipate that intellectual property barriers and FDA regulatory exclusivity will be the primary means to protect the commercial potential of Vascepa, the availability of Vascepa active pharmaceutical ingredient from our suppliers to our potential competitors would make our competitors’ entry into the market easier and more attractive.”).

Pharma Inc. (“Nisshin”) pursuant to which Nisshin agreed to supply Amarin with IPE (referred to as E-EPA in the agreement).³⁶ Amarin paid Nisshin \$500,000 when the agreement was signed, and agreed to pay Nisshin another \$500,000 when Amarin obtained approval to market Vascepa either in the U.S. or the European Union.³⁷ The agreement contained a minimum purchase commitment.³⁸

133. Amarin believed that Nisshin was capable of producing sufficient quantities of API to support Amarin’s launch of Vascepa.³⁹ Nonetheless, it continued to amass API supply and suppliers.

134. In June 2011, the BBC reported that Amarin had entered into a supply agreement with Scotland-based Equateq Ltd. (“Equateq”) pursuant to which Equateq agreed to supply Amarin with the API needed to manufacture Vascepa.⁴⁰ Amarin again committed to significant, long-term purchases: “Under the terms of the contract, Amarin Corporation is committed to buying £6.1m worth of API concentrate from Equateq in year one, rising to £12.3m in year four.”⁴¹ In fact, although the CEO of Equateq refused to provide further specifics of the supply agreement, he claimed it was worth £100m over its life.⁴² Amarin revealed to investors in August 2011

³⁶ Supply Agreement Between (1) Nisshin Pharma Inc. (“Nisshin”) and (2) Amarin Pharmaceuticals (Ireland) Ltd. (“Amarin”), dated Feb. 23, 2009, https://www.sec.gov/Archives/edgar/data/897448/000095016209000453/ex4_86.htm.

³⁷ *Id.* at 15.

³⁸ *Id.*

³⁹ Amarin Corp. plc, Annual Report (Form 10-K), at 10-11 (Feb. 29, 2012); *see also* Press Release, Amarin Corp. plc, “Amarin Announces Additional Vascepa® (icosapent ethyl) Supplier” (Dec. 11, 2012) (“Amarin’s current plan is to launch Vascepa based on product produced by its existing API supplier, Nisshin Pharma”), <https://www.globenewswire.com/en/news-release/2012/12/11/510754/18362/en/Amarin-Announces-Additional-Vascepa-R-icosapent-ethyl-Supplier.html>.

⁴⁰ “Drug firm Equateq secures big US order,” BBC News (July 4, 2011), <https://www.bbc.com/news/uk-scotland-scotland-business-14013747>

⁴¹ *Id.*

⁴² “Equateq nets £100m deal to supply fish oil for heart treatment,” The Scotsman (June 29, 2011), <https://www.scotsman.com/business/equateq-nets-ps100m-deal-supply-fish-oil-heart->

that the minimum purchase commitment was intended to prevent Equateq from selling Vascepa API to any potential competitor of Amarin.⁴³ Amarin also paid Equateq a \$1m “commitment fee” in May 2011.⁴⁴ Equateq was acquired by BASF in May 2012.⁴⁵

135. Also in 2011, Amarin secured an exclusive supply contract with Korea-based Chemport Inc. (“Chemport”).⁴⁶ This agreement also contains minimum purchase requirements to prevent Chemport from selling API to potential generic manufacturers,⁴⁷ and Amarin is required to pay Chemport in cash for any shortfall in the minimum purchase obligations.⁴⁸ As part of the agreement, Amarin agreed to pay Chemport \$1.1m for the purchase of raw materials and to provide an additional \$3.3m to Chemport as equity investment.⁴⁹ During a nine month period ending September 30, 2013, the Company made payments of \$4.8 million to Chemport.⁵⁰

136. Equateq and Chemport were approved by the FDA to manufacture Vascepa API in April 2013.⁵¹

137. In December 2012, Amarin announced that it had entered into an additional exclusive agreement with a fourth supplier, an “exclusive consortium” of companies including

[treatment-1670500.](#)

⁴³ Amarin Corp. plc Quarterly Report (Form 10-Q), at 9 (Aug. 9, 2011) (“Following FDA approvals of [Vascepa], both agreements [with Equateq and Chemport Inc.] include annual purchase levels *to enable Amarin to maintain exclusivity with each respective supplier*, and to prevent potential termination of the agreements.”).

⁴⁴ *Id.*

⁴⁵ “BASF completes omega-3 portfolio with Equateq buy,” NUTRAingredients.com (May 8, 2012), <https://www.nutraingredients.com/Article/2012/05/09/BASF-completes-omega-3-portfolio-with-Equateq-buy#>

⁴⁶ Amarin Corp. plc Quarterly Report (Form 10-Q), at 9 (Aug. 9, 2011).

⁴⁷ *Id.* (“Following FDA approvals of [Vascepa], both agreements [with Equateq and Chemport] include annual purchase levels *to enable Amarin to maintain exclusivity with each respective supplier*, and to prevent potential termination of the agreements.”).

⁴⁸ Amarin Corp. plc Annual Report (Form 10-K), at F-25 (Feb. 27, 2014).

⁴⁹ *Id.*

⁵⁰ Amarin Corp. plc Quarterly Report (Form 10-Q), at 15 (Nov. 7, 2013).

⁵¹ Amarin Corp. plc Quarterly Report (Form 10-Q), at 13 (May 9, 2013).

Canada-based Slanmhor Pharmaceutical, Inc., Ocean Nutrition Canada, and Novasep (collectively referred to in this Complaint as “Novasep”).⁵² As part of the agreement, Amarin agreed to pay up to \$2.3 million in development fees and a “commitment” of up to \$15 million, credited against future API material purchase.⁵³ The Company made payments of \$3.9 million to Novasep in the quarter in which the agreement was signed,⁵⁴ and an additional \$1.4 million in the following quarter.⁵⁵ The Novasep agreement includes minimum purchase obligations, and Amarin is required to make cash payments to Novasep in the event of a shortfall.⁵⁶ During the nine month period ending September 30, 2013, the Company made payments of \$6.1 million to Novasep.⁵⁷ In July 2014, Amarin cancelled the agreement with the consortium and, in July 2015, it entered a new agreement with Novasep in its own right.⁵⁸

138. The Company purchased approximately \$25.7 million worth of Vascepa API in 2013 from Nisshin and Chemport, and also paid \$13.9 million to Novasep related to “commitments,” stability and technical batches, and advances on future API purchases.⁵⁹

139. In October 2013, Amarin received bad news from the FDA which “was seen by most observers as the death blow for Amarin’s efforts to gain wider approval.”⁶⁰

140. Although this was expected to result in less-than-hoped-for demand for Vascepa,

⁵² Press Release, Amarin Corp. plc, “Amarin Announces Additional Vascepa® (icosapent ethyl) Supplier” (Dec. 11, 2012).

⁵³ Amarin Corp. plc Quarterly Report (Form 10-Q), at 13 (May 9, 2013).

⁵⁴ *Id.*

⁵⁵ Amarin Corp. plc Quarterly Report (Form 10-Q), at 15 (Aug. 8, 2013).

⁵⁶ *Id.*

⁵⁷ Amarin Corp. plc Quarterly Report (Form 10-Q), at 15 (Nov. 7, 2013).

⁵⁸ Amarin Corp. plc Annual Report (Form 10-K), at 14 (Feb. 25, 2016).

⁵⁹ Amarin Corp. plc Quarterly Report (Form 10-Q), at 33 (Nov. 7, 2013).

⁶⁰ “Novasep to keep supplying Amarin with Vascepa API,” Outsourcing-Pharma.com (Oct. 30, 2012), <https://www.outsourcing-pharma.com/Article/2013/10/30/Novasep-to-keep-supplying-Amarin-with-Vascepa-API>

Novasep and BASF planned to continue supplying Vascepa API at the agreed-upon pace.⁶¹

141. Finally, Amarin has secured significant additional supply from another Japan-based supplier, Nippon Suisan, and that company's supply is not available to any U.S. generic.⁶²

142. The foregoing agreements between Amarin and the Vascepa API suppliers were intended to and have limited competition in the market for generic Vascepa. The API suppliers took millions of dollars in payments from Amarin in exchange for an agreement *not* to sell the essential API, regardless of whether Amarin needed the API for its own production needs or whether there were other market opportunities for the sale of the API. By foreclosing API supply from generic competitors, Amarin has been able to capture supra-competitive profits from the inflated sales of Vascepa, and has shared those supra-competitive profits with the API suppliers to buy their complicity in the anticompetitive scheme.

G. Amarin secured more than twice the API supply than it needs for legitimate business purposes

143. In February 2019, Amarin's CEO John Thero stated that Amarin's anticipated 2019 sales of Vascepa amounted to \$350 million, but the company was purchasing API to support sales of more than \$700 million.⁶³ Thero was clear that Amarin was *not* raising its guidance or expecting to sell more than \$700 million in Vascepa that year, but was merely purchasing excess supply.⁶⁴

⁶¹ *Id.*

⁶² "Amarin: What The Street Hasn't Factored In And Why Amarin Is Worth \$80," Seeking Alpha (Oct. 9, 2018) ("Nippon Suisan (1332 JT), or better known as "Nissui" in the Japanese stock market, has 420 tons worth of annual high-grade EPA supply, solely aimed for the further roll-out of Amarin's Vascepa."), <https://seekingalpha.com/article/4210747-amarin-what-street-hasn-t-factored-in-and-why-amarin-is-worth-80>

⁶³ Amarin Corp. plc Earnings Call (Feb. 27, 2019), <https://www.fool.com/earnings/call-transcripts/2019/02/27/amarin-corporation-plc-amrn-q4-2018-earnings-confe.aspx>

⁶⁴ *Id.* ("Hey, we could be wrong on our guidance. Our guidance doesn't assume any earlier approval from the FDA. And they had their mind to our product as four-year dating. Dating, one of the things we spent a lot of time in the development of this product was the stability of it and

144. At the same time that Amarin was purchasing more than twice its supply needs for 2019 from its existing suppliers, Amarin was in the process of locking up 420 tons worth of additional annual supply.⁶⁵ For comparison, the entire U.S. market for Vascepa is estimated to require 450 tons of API per year.

H. Amarin’s excess supply makes no economic sense absent anticompetitive advantages, and is contrary to industry practice

145. In Amarin’s own words: “The agreements with each of our API suppliers contemplate phased manufacturing capacity expansions designed to create sufficient manufacturing capacity to meet anticipated demand for API material for [Vascepa] following FDA approval. Accordingly, Nisshin and our other potential suppliers are currently working to expand and qualify their production capabilities to meet regulatory requirements to manufacture the API for [Vascepa]. These API suppliers are self-funding these expansion and qualification plans *with contributions from Amarin.*”⁶⁶

146. Amarin provided further detail about the expenses necessary to develop and maintain so many API suppliers: “Among the conditions for FDA approval of a pharmaceutical product is the requirement that the manufacturer’s quality control and manufacturing procedures conform to current Good Manufacturing Practice, or cGMP, which must be followed at all times. The FDA typically inspects manufacturing facilities before regulatory approval of a product candidate, such as [Vascepa], and on an ongoing basis. In complying with cGMP regulations,

preventing oxidation, etc. So, it’s got a long shelf life. So, they figure that that’s the right investment to be made.”).

⁶⁵ “Amarin: What The Street Hasn’t Factored In And Why Amarin Is Worth \$80,” Seeking Alpha (Oct. 9, 2018), <https://seekingalpha.com/article/4210747-amarin-what-street-hasnt-factored-in-and-why-amarin-is-worth-80> (“Nippon Suisan (1332 JT), or better known as ‘Nissui’ in the Japanese stock market, has 420 tons worth of annual high-grade EPA supply, solely aimed for the further roll-out of Amarin’s Vascepa.”).

⁶⁶ Amarin Corp. plc Annual Report (Form 10-K), at 11 (Feb. 20, 2012) (emphasis added).

pharmaceutical manufacturers must expend resources and time to ensure compliance with product specifications as well as production, record keeping, quality control, reporting, and other requirements. Our NDA filed with the FDA for [Vascepa] references one supplier of our API, Nisshin, with which we have had the longest relationship and which we believe is qualified to support our initial commercial launch of [Vascepa]. We have defined with the FDA our plan and specifications for qualifying the additional API suppliers. We intend to submit sNDAs^[67] for the use of these additional API suppliers after the suppliers successfully complete the specified process and facility qualifications and after the NDA for the MARINE indication is approved.”⁶⁸

147. As these public statements confirm, it is expensive and time consuming for each new API supplier to develop, obtain regulatory approval for, and maintain quality control of its API manufacturing process, and Amarin bears a significant share of that burden.

148. On the other hand, it is possible⁶⁹ and less expensive to scale up the supply from an existing manufacturer than it is to qualify additional suppliers. Consequently, standard industry practice is to have only one or two API suppliers.

149. In addition to saving initial setup costs, the benefits of scale result in volume discounts,⁷⁰ which Amarin foregoes by engaging additional suppliers with minimum purchase

⁶⁷ Defined in paragraph 68 above.

⁶⁸ *Id.*; see also Amarin Corp. plc Quarterly Report, at 16 (Nov. 8, 2011) (“We anticipate incurring certain costs associated with the qualification of product produced by [Nisshin, Equateq, and Chemport].”).

⁶⁹ Amarin Corp. plc Annual Report (Form 10-K), at 75 (Feb. 27, 2019) (“our current supply chain is scalable”); see also, Amarin Corp. plc Earnings Conference Call Transcript (Feb. 27, 2019) (“We have a supplier network that consists of over 20 independent companies. The API piece of that – we have multiple suppliers on. They’re competing with one another. ***And they’re interested in expanding capacity.***”), <https://www.fool.com/earnings/call-transcripts/2019/02/27/amarin-corporation-plc-amrn-q4-2018-earnings-confe.aspx>

⁷⁰ Amarin Corp. plc Annual Report (Form 10-K), at 75 (Feb. 27, 2019) (“Certain of our API supply agreements contain provisions under which the cost of supply to us decreases as we purchase increased product volume.”).

requirements.

150. Given these inefficiencies, the only economic advantages from having four API suppliers, and obtaining excess API inventory, results from the inability of generic competitors to obtain API supply.

I. Amarin's scheme succeeded in thwarting generic competition

151. DRL obtained final FDA approval on August 7, 2020,⁷¹ but was unable to secure a supply of API sufficient to support a launch of its generic Vascepa until June 22, 2021.⁷²

152. Hikma, on the other hand, was able to launch on November 5, 2020,⁷³ but was forced to release limited quantities due to supply constraints.⁷⁴

153. For its part, Amarin believes its scheme is working, and wants the market to know: “We have heard from various suppliers that they have been approached regarding supplying API for generic use. These suppliers informed us that they turned down such approaches for

⁷¹ Product Details for ANDA 209400, https://www.accessdata.fda.gov/scripts/cder/ob/results_product.cfm?Appl_Type=A&Appl_No=09499#312

⁷² DRL Complaint at ¶ 81 (“Nonetheless, despite DRL’s best efforts to launch in a timely manner, it is still unable to do so. The only reason why DRL still cannot launch is because Amarin contracted with suppliers of icosapent ethyl API not to sell to generic manufacturers including DRL, either through literal exclusive contract or through buying up all available supplies, such that DRL cannot acquire the necessary API to support a timely commercial launch.”); *id.* at ¶ 8 (“But for Amarin’s locking up of the icosapent ethyl API supply, DRL would have been ready, willing, and able to launch in August 2020, upon receiving regulatory approval.”). *See also* Press Release, Dr. Reddy’s Laboratories Ltd, “Dr. Reddy’s Laboratories Announces the Launch of Icosapent Ethyl Capsules, 1 Gram in the U.S. Market” (June 22, 2021), <https://www.bloomberg.com/press-releases/2021-06-22/dr-reddy-s-laboratories-announces-the-launch-of-icosapent-ethyl-capsules-1-gram-in-the-u-s-market>.

⁷³ Press Release, Hikma Pharmaceuticals plc, “Hikma launches Icosapent Ethyl Capsules” (Nov. 5, 2020), <https://www.hikma.com/newsroom/article-i4928-hikma-launches-icosapent-ethyl-capsules/>

⁷⁴ Amarin launches Vascepa in all-important Europe as it slowly bleeds share to U.S. generic,” Fierce Pharma (Apr. 6, 2021), <https://www.fiercepharma.com/marketing/amarin-launches-vascepa-all-important-europe-as-blockbuster-to-be-heart-drug-slowly>

various reasons including that they don't have excess capacity.”⁷⁵ And in a press release discussing the Court of Appeals decision Amarin knowingly conveyed that generic manufacturers “are likely to have limited supply capacity.”⁷⁶

DEFENDANTS ANTITRUST VIOLATIONS

154. As a result of the anticompetitive conduct engaged in by Amarin, generic icosapent ethyl would have entered the market no later than January 2020, because no sham litigation would have delayed regulatory approval and launch and because there would have been sufficient supply of Vascepa API for generic manufacturers.

155. Instead, Amarin willfully and unlawfully maintained its monopoly in the relevant market by initiating sham patent litigation and engaging in actions designed to exclude competition and maintain supra-competitive prices for Vascepa. Amarin implemented and maintained its monopoly through the exclusive contracts it entered with its co-conspirators as well as other conduct alleged herein.

156. The only impediment to DRL's generic icosapent ethyl entering the market by January 2020 or upon receiving final approval was Defendants' unlawful conduct.

157. Likewise, the only impediment to Hikma entering the market by January 2020 and/or fully supplying demand for generic icosapent ethyl is Defendant' unlawful conduct.

158. While the full effect of Amarin's conduct will be the subject of discovery, absent the sham patent litigation it engaged in, other generic manufacturers might have altered their ANDA activities so as to be in a position to receive final approval and launch by January 2020.

⁷⁵ Amarin Corp. plc Earnings Call Transcript (Apr. 13, 2020), <https://www.fool.com/earnings/call-transcripts/2020/04/13/amarin-corporation-plc-amrn-q1-2020-earnings-call.aspx>

⁷⁶ Press Release, Amarin Corp. plc, “Amarin Provides Update Following Ruling in Vascepa® ANDA Patent Litigation” (Sept. 3, 2020), <https://investor.amarincorp.com/news-releases/news-release-details/amarin-provides-update-following-ruling-vascepar-anda-patent>.

159. Amarin's actions had the purpose and effect of preventing competition to Vascepa, permitting Amarin to maintain supra-competitive prices for Vascepa, enabling Amarin to sell Vascepa without competition, and allowing Amarin to reap monopoly profits (and share those monopoly profits with its API- supplier co-conspirators), to the detriment of purchasers.

The Market For Vascepa

160. Throughout the relevant time period, Amarin had monopoly power in the market for Vascepa because they had the power to exclude competition and/or raise or maintain the price of Vascepa and generic equivalents at supra-competitive levels without losing enough sales to make supra-competitive prices unprofitable.

161. Brand Vascepa does not exhibit significant, positive cross-elasticity of demand with respect to price with any other product for the treatment of hypertriglyceridemia.

162. Brand Vascepa is differentiated from all other products currently on the market for treatment of hypertriglyceridemia.

163. Amarin needed to control only brand Vascepa and its AB-rated generic equivalents, and no other products, in order to maintain the price of icosapent ethyl profitably at supra-competitive prices. Only the market entry of competing, AB-rated generic versions of Vascepa unconstrained by supply issues would render Amarin unable to profitably maintain their prices for Vascepa without losing substantial sales.

164. Amarin had, and exercised, the power to exclude generic competition to brand Vascepa.

165. At all material times, high barriers to entry protected brand Vascepa from the forces of price competition.

166. There is direct evidence of market power and anticompetitive effects available in

this case sufficient to show Amarin's ability to control the price of Vascepa and generic Vascepa, and to exclude relevant competitors, without the need to show the relevant antitrust markets. The direct evidence consists of, inter alia, the following facts: (a) generic Vascepa would have entered the market at a substantial discount to brand Vascepa but for Defendants' anticompetitive conduct; (b) Amarin's gross margin on Vascepa at all relevant times was very high; and (c) Amarin never lowered the price of Vascepa to the competitive level in response to the pricing of other brand or generic drugs, and indeed enjoyed rising sales as it dramatically increased the price of Vascepa.

167. To the extent proof of monopoly power by defining a relevant product market is required, Plaintiff alleges that the relevant antitrust market is the market for Vascepa and its AB-rated generic equivalents.

168. The United States, the District of Columbia, and the U.S. territories constitute the relevant geographic market.

169. Amarin market share in the relevant market was 100% prior to Hikma's constrained generic launch, implying substantial monopoly power.

EFFECTS

170. Amarin willfully and unlawfully maintained their market power by engaging in an overarching scheme to exclude competition. Amarin designed a scheme to delay competition on the products' merits to further Amarin's anticompetitive purpose of forestalling generic competition against Vascepa. Amarin carried out the scheme with the anticompetitive intent and effect of maintaining supra-competitive prices for icosapent ethyl.

171. These acts and practices had the purpose and effect of restraining competition unreasonably and injuring competition by protecting brand Vascepa from competition. These actions allowed Amarin to maintain a monopoly and exclude competition in the market for

Vascepa and its AB-rated generic equivalents, to the detriment of Plaintiff and all other members of the Classes.

172. Amarin's exclusionary conduct delayed and limited generic competition and unlawfully enabled Amarin to sell Vascepa without generic competition or with limited generic competition. Were it not for Amarin's illegal conduct, one or more generic versions of Vascepa would have entered the market sooner.

173. Amarin's anticompetitive conduct caused Plaintiff and all members of the Classes to pay more than they would have paid for Vascepa and generic equivalents absent their illegal conduct.

174. If generic competitors had not been unlawfully prevented from entering the market earlier and competing in the relevant markets, Plaintiff and members of the Classes would have paid less for icosapent ethyl by (a) paying lower prices on their remaining brand purchases of Vascepa, and/or (b) substituting purchases of less-expensive generic Vascepa for their purchases of more-expensive brand Vascepa.

ANTITRUST IMPACT AND INJURY TO PLAINTIFF AND THE CLASSES

175. During the relevant time period, Plaintiff and members of the Classes purchased substantial amounts of Vascepa indirectly from Amarin. As a result of this illegal conduct, Plaintiff and the members of the Classes were compelled to pay, and did pay, artificially inflated prices for Vascepa. Those prices were substantially greater than the prices that Plaintiff and members of the Classes would have paid absent the illegal conduct alleged herein, because: (1) the price of brand-name Vascepa was artificially inflated by Amarin's illegal conduct, and (2) Plaintiff and members of the Classes have been deprived of the opportunity to purchase lower-priced generic versions of Vascepa.

176. As a consequence of these actions, Plaintiff and members of the Classes have sustained substantial damages to their business and property in the form of overcharges. The full amount and form of such damages will be calculated after discovery and upon proof at trial. Commonly used and well-accepted economic models can be used to measure both the extent and the amount of the supra-competitive charge passed through the chain of distribution to Plaintiff and the members of the Classes.

177. These anticompetitive actions enabled Amarin to charge Plaintiff and the Classes prices in excess of what it otherwise would have been able to charge absent its unlawful agreements described herein.

178. Prices for Vascepa were inflated as a direct and foreseeable result of this anticompetitive conduct.

TRADE AND COMMERCE

179. During the relevant time period, Amarin used various devices to effectuate the illegal acts alleged herein, including the United States mail, interstate and foreign travel, and interstate and foreign wire commerce. The acts engaged herein were within the flow of, and substantially affected, interstate commerce.

180. During the relevant time period, brand Vascepa, manufactured and sold by Amarin, was shipped into each state and was sold to or paid for by Plaintiff and members of the Classes.

181. During the relevant time period, in connection with the purchase and sale of brand Vascepa, money exchanged hands and business communications and transactions occurred in each state.

CLASS ACTION ALLEGATIONS

182. Plaintiff brings this action on its own behalf and on behalf of all others similarly

situated pursuant to Rules 23(a) and 23(b)(3) of the Federal Rules of Civil Procedure (“Damages Class”):

All persons and entities who indirectly purchased, paid and/or provided reimbursement for some or all of the purchase price for Vascepa, other than for resale, in the States of Alabama, Alaska, Arizona, Arkansas, California, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Idaho, Illinois, Iowa, Kansas, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Montana, Nebraska, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, North Dakota, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Utah, Vermont, Virginia, Washington, West Virginia, Wisconsin, Wyoming, the District of Columbia, and Puerto Rico, at any time during the period from January 27, 2020 through and until the anticompetitive effects of Defendants’ challenged conduct cease (the “Class Period”).

183. Plaintiff brings this action on its own behalf and on behalf of all others similarly situated pursuant to Rules 23(a) and 23(b)(2) of the Federal Rules of Civil Procedure (“Injunctive Relief Class”)

All persons and entities who purchased, paid and/or provided reimbursement for some or all of the purchase price for Vascepa, other than for resale, in the United States at any time during the period from January 27, 2020 through and until the anticompetitive effects of Defendants’ challenged conduct cease (the “Class Period”).

184. Excluded from the Classes are:

- a. Defendants and their counsel, officers, directors, management, employees, subsidiaries, and affiliates;
- b. all federal governmental entities;
- c. all persons or entities who purchased Vascepa for purposes of resale or directly from Amarin or their affiliates;
- d. fully insured health plans (*i.e.*, health plans that purchased insurance from another third-party payer covering 100% of the plan’s reimbursement obligations to its members);
- e. any “flat co-pay” consumers whose purchases of Vascepa were paid in part by a third-party payer and whose co-payment was the same regardless of the retail purchase price;
- f. pharmacy benefit managers;

- g. all counsel of record; and
- h. all judges assigned to this case and any members of their immediate families.

185. The Classes are so numerous that joinder is impracticable. While the exact number of class members is unknown to Plaintiff at this time, Plaintiff is informed and believes there are hundreds of thousands of class members geographically dispersed throughout the United States.

186. Plaintiff's claims are typical of the claims of the other members of the Classes. Plaintiff and members of the Classes sustained damages as a result of the same wrongful conduct by Amarin, and all paid artificially inflated prices for Vascepa.

187. Plaintiff will fairly and adequately protect and represent the interests of the members of the Classes and has retained counsel experienced in prosecuting actions of this type. Plaintiff's interests are coincident with, and not antagonistic to, the interests of the Classes it seeks to represent.

188. Common questions of law and fact exist as to all members of the Classes, which predominate over any questions affecting solely individual members of the Classes. Among the questions common to the Classes are the following:

- a. whether Amarin unlawfully maintained monopoly power;
- b. whether Amarin's anticompetitive conduct suppressed generic competition in the marketing and sale of Vascepa;
- c. whether Defendants' conduct, in whole or in part, has substantially affected intrastate commerce;
- d. whether Amarin, through its exclusive supply arrangements, foreclosed the supply of icosapent ethyl;
- e. whether Defendants' conduct caused antitrust injury to the business or property of Plaintiff and members of the Classes; and
- f. the appropriate measure of damages for the injury sustained by Plaintiff and the other members of the Classes as a result of Defendants' unlawful actions.

189. Defendants acted or refused to act on grounds that apply generally to the Classes

so that final injunctive relief or corresponding declaratory relief would be appropriate respecting the Class as a whole.

190. A class action is superior to other methods for the fair and efficient adjudication of this controversy in that joinder of all class members is impracticable. The prosecution of separate actions by individual members of the class would impose heavy burdens upon the courts and defendants, and would create a risk of varying or inconsistent adjudications of the questions of law and act common to the class. A class action, on the other hand, would achieve substantial economies of time, effort and expense and would afford uniformity of decision as to persons similarly situated without sacrificing procedural fairness or bringing about other undesirable results.

191. The interests of members of the classes in individually controlling separate actions is theoretical rather than practical. The Classes have a high degree of cohesion, and prosecution of the action through representatives would be unobjectionable. The amounts at stake for class members, while substantial in the aggregate, are not great enough individually to enable them to maintain separate suits against defendant. Plaintiff does not anticipate any difficulty in maintaining this action as a class action.

CLAIMS FOR RELIEF
COUNT ONE
For Monopolization
Under State Law

192. Plaintiff incorporates by reference all of the allegations above as though fully set forth herein.

193. Plaintiff brings this claim on behalf of the Damages Class.

194. The relevant market consists of Vascepa and its generic equivalents.

195. As described above, throughout the relevant time period Amarin possessed

monopoly power nationwide and in each of the state and its territories in the market for Vascepa and its generic equivalents.

196. At all relevant times, Amarin possessed substantial market power (*i.e.*, monopoly power) in the relevant market. Amarin possessed the power to control prices in, prevent prices from falling in, and exclude competitors from the relevant market.

197. Through their overarching anticompetitive scheme, as alleged above, Amarin willfully maintained their monopoly power in the relevant market using restrictive or exclusionary conduct, rather than by means of greater business acumen or a historic accident, and thereby injured Plaintiff and the Class. Amarin's anticompetitive conduct was done with the specific intent to maintain its monopoly in the market for Vascepa in the United States.

198. Amarin knowingly and intentionally engaged in this anticompetitive scheme to monopolize the Vascepa market as described above. Amarin accomplished this scheme by, *inter alia*, (1) initiating sham litigation against generic manufacturers seeking to enter the market; (2) entering into exclusive supply agreements with at least four different icosapent ethyl API suppliers; (3) otherwise foreclosing the supply of icosapent ethyl API; and (4) raising and maintaining prices so that Plaintiff and members of the Class would pay for Vascepa at supra-competitive prices.

199. The goal, purpose, and effect of Amarin's scheme was to prevent and delay the sale of generic Vascepa in the United States at prices significantly below Amarin's prices for Vascepa, thereby effectively preventing the average market price of Vascepa and its generic equivalents from declining dramatically.

200. The goal, purpose, and effect of Amarin's scheme was also to maintain and extend its monopoly power with respect to Vascepa and its generic equivalents. Amarin's illegal scheme allowed it to continue charging supra-competitive prices for Vascepa, without a substantial loss of

sales, reaping substantial unlawful monopoly profits.

201. Plaintiff and members of the Damages Class purchased substantial amounts of Vascepa indirectly from Amarin.

202. As a result of Amarin's illegal conduct, Plaintiff and members of the Damages Class were compelled to pay, and did pay, more than they would have paid for their requirements of Vascepa and its generic equivalents absent Amarin's illegal conduct. But for Amarin's illegal conduct, competitors would have begun selling generic Vascepa during the relevant period, and prices for Vascepa and its generic equivalents would have been lower, sooner.

203. Had manufacturers of generic Vascepa entered the market and lawfully competed with Amarin earlier, Plaintiff and other members of the Damages Class would have substituted lower-priced generic Vascepa for the higher-priced brand-name Vascepa for some or all of their requirements of Vascepa and its generic equivalents, and/or would have paid lower net prices on their remaining Vascepa and/or AB-rated bioequivalent purchases.

204. By engaging in the foregoing conduct, Amarin violated the following state antitrust laws:

- a. Arizona Rev. Stat. §§ 44-1403, *et seq.*, with respect to purchases of Vascepa in Arizona by members of the Damages Class.
- b. Cal. Bus. & Prof. Code §§ 16700, with respect to purchases of Vascepa in California by members of the Damages Class.
- c. C.G.S.A. §§ 35-27, *et seq.*, with respect to purchases of Vascepa in Connecticut by members of the Damages Class.
- d. D.C. Code §§ 28-4503, *et seq.*, with respect to purchases of Vascepa in the District of Columbia by members of the Damages Class.
- e. Hawaii Rev. Stat. §§ 480-1, *et seq.* with respect to purchases of Vascepa in Hawaii by members of the Damages Class.
- f. Illinois Antitrust Act, 740 Illinois Compiled Statutes 10/1, *et seq.*, with respect to purchases of Vascepa in Illinois by members of the Damages Class.
- g. Iowa Code §§ 553.5 *et seq.*, with respect to purchases of Vascepa and AB-

rated bioequivalents in Iowa by members of the Damages Class.

- h. Kansas Stat. Ann. §§ 50-101 *et seq.*, with respect to purchases of Vascepa and AB-rated bioequivalents in Kansas by members of the Damages Class.
- i. Me. Rev. Stat. Ann. 10, §§ 1102, *et seq.*, with respect to purchases of Vascepa and AB-rated bioequivalents in Maine by consumer members of the Damages Class.
- j. Md. Com'l Law Code Ann. §§ 11-204(a), *et seq.*, with respect to purchases of Vascepa and AB-rated bioequivalents in Maryland by members of the Damages Class.
- k. Mich. Comp. Laws Ann. §§ 445.773, *et seq.*, with respect to purchases of Vascepa and AB-rated bioequivalents in Michigan by members of the Damages Class.
- l. Minn. Stat. §§ 325D.49, *et seq.*, and Minn. Stat. §§ 8.31, *et seq.*, with respect to purchases of Vascepa and AB-rated bioequivalents in Minnesota by members of the Damages Class.
- m. Miss. Code Ann. §§ 75-21-3, *et seq.*, with respect to purchases of Vascepa and AB-rated bioequivalents in Mississippi by members of the Damages Class.
- n. Neb. Code Ann. §§ 59-802, *et seq.*, with respect to purchases of Vascepa and AB-rated bioequivalents in Nebraska by members of the Damages Class.
- o. Nev. Rev. Stat. Ann. §§ 598A.060, *et seq.*, with respect to purchases of Vascepa and AB-rated bioequivalents in Nevada by members of the Damages Class.
- p. N.H. Rev. Stat. Ann. §§ 356.11, *et seq.*, with respect to purchases of Vascepa and AB-rated bioequivalents in New Hampshire by members of the Damages Class.
- q. N.M. Stat. Ann. §§ 57-1-2, *et seq.*, with respect to purchases of Vascepa and AB-rated bioequivalents in New Mexico by members of the Damages Class.
- r. N.Y. Gen. Bus. Law §§ 340, *et seq.*, with respect to purchases of Vascepa and AB-rated bioequivalents in New York by members of the Damages Class.
- s. N.C. Gen. Stat. §§ 75-2.1, *et seq.*, with respect to purchases of Vascepa and AB-rated bioequivalents in North Carolina by members of the Damages Class.
- t. N.D. Cent. Code §§ 51-08.1-03, *et seq.*, with respect to purchases of Vascepa and AB-rated bioequivalents in North Dakota by members of the Damages Class.
- u. Or. Rev. Stat. §§ 646.730, *et seq.*, with respect to purchases of Vascepa and

AB-rated bioequivalents in Oregon by members of the Damages Class.

- v. R.I. Gen. Laws §§ 6-36-5 *et seq.*, with respect to purchases of Vascepa and AB-rated bioequivalents in Rhode Island by members of the Damages Class.
- w. S.D. Codified Laws §§ 37-1-3.2, *et seq.*, with respect to purchases of Vascepa and AB-rated bioequivalents in South Dakota by members of the Damages Class.
- x. Tenn. Code Ann. §§ 47-25-101, *et seq.*, with respect to purchases of Vascepa and AB-rated bioequivalents in Tennessee by members of the Damages Class.
- y. Utah Code Ann. §§ 76-10-911, *et seq.*, with respect to purchases of Vascepa and AB-rated bioequivalents in Utah by members of the Damages Class.
- z. Vt. Stat. Ann. 9, §§ 2453, *et seq.*, with respect to purchases of Vascepa and AB-rated bioequivalents in Vermont by consumer members of the Damages Class.
- aa. W.Va. Code §§ 47-18-4, *et seq.*, with respect to purchases of Vascepa and AB-rated bioequivalents in West Virginia by members of the Damages Class.
- bb. Wis. Stat. §§ 133.03, *et seq.*, with respect to purchases of Vascepa and AB-rated bioequivalents in Wisconsin by members of the Damages Class.

205. Plaintiff and members of the Damages Class have been injured in their business or property by reason of Amarin's antitrust violations alleged in this Claim. Their injuries consist of: (1) being denied the opportunity to purchase lower-priced generic Vascepa, and (2) paying higher prices for Vascepa and its generic equivalents than they would have paid in the absence of Amarin's conduct. These injuries are of the type that the antitrust laws were designed to prevent, and flow from that which makes Amarin's conduct unlawful.

206. Plaintiff and the Damages Class seek damages and multiple damages as permitted by law for their injuries by Amarin's violations of the aforementioned statutes.

COUNT TWO

Unfair or Deceptive Trade Practices

207. Plaintiff incorporates by reference all of the allegations above as though fully set

forth herein.

208. Plaintiff brings this claim on behalf of the Damages Class.

209. Defendants engaged in unfair competition, and/or unfair/unconscionable, and/or deceptive acts or practices in violation of the state consumer protection statutes listed below. As a direct and proximate result of Defendants' anticompetitive, deceptive, unfair and/or unconscionable acts or practices, Plaintiff and Damages Class members were deprived of the opportunity to purchase a less expensive AB-rated bioequivalent of Vascepa and forced to pay higher prices in violation of the following consumer protection statutes:

- a. Alaska Stat. Ann. §§ 45.50.471, *et seq.*, with respect to purchases in Alaska by members of the Damages Class. Defendants engaged in unfair methods of competition and unfair practices in the conduct of trade and commerce.
- b. Cal. Bus. & Prof. Code §§ 17200, *et seq.*, with respect to purchases in California by members of the Damages Class. Defendants engaged in business practices that are unfair in that they are immoral, unethical, oppressive, unscrupulous, and substantially injurious to Damages Class members. There are no countervailing benefits to Damages Class members and any utility of Defendants' conduct is outweighed by the consequences to Damages Class members.
- c. Fla. Stat. §§ 501.201, *et seq.*, with respect to purchases in Florida by members of the Damages Class.
- d. Mo. Rev. Stat. §§ 407.020, *et seq.*, with respect to purchases in Missouri by consumer members of the Damages Class.
- e. Mont. Code Ann. §§ 30-14-101, *et seq.*, with respect to purchases in Montana by consumer members of the Damages Class. Defendants engaged in unfair and deceptive acts and practices.
- f. S.C. Code Ann. §§ 39-5-20, *et seq.*, with respect to purchases in South Carolina by Damages Class members. Defendants engaged in unfair methods of competition and unfair practices in the conduct of trade and commerce. Defendants' conduct is offensive to public policy and immoral, unethical, and oppressive.
- g. Vt. Stat. Ann. 9, §§ 2453, *et seq.*, with respect to purchases in Vermont by consumer members of the Damages Class. Defendants engaged in unfair methods of competition, unfair practices, and deceptive practices in the conduct of trade and commerce.

210. Plaintiff and members of the Damages Class have been injured in their business

and property by reason of Defendants' anticompetitive, unfair/unconscionable, and/or deceptive acts or practices alleged in this Count. Their injury consists of paying higher prices for Vascepa and/or AB-rated generic bioequivalents than they would have paid in the absence of these violations. This injury is of the type the state consumer protection statutes were designed to prevent and directly results from Defendants' unlawful conduct.

COUNT THREE
Unjust Enrichment Under State Law

211. Plaintiff incorporates by reference all of the allegations above as though fully set forth herein.

212. Plaintiff brings this claim on behalf of the Damages Class.

213. To the extent required, this claim is pleaded in the alternative to the other claims in this complaint.

214. As a result of their unlawful conduct described above, Defendants have and will continue to be unjustly enriched. Defendants have been unjustly enriched by the receipt of, at a minimum, unlawfully inflated prices and unlawful profits on Vascepa.

215. Defendants' financial benefits are traceable to Plaintiff's and Damages Class members' overpayments for Vascepa.

216. Plaintiff and Damages Class members have conferred and continue to confer an economic benefit upon Defendants in the nature of profits resulting from the unlawful overcharges described herein, to the economic detriment of Plaintiff and Damages Class members.

217. Defendants have benefited from its unlawful acts and it would be inequitable for Defendants to be permitted to retain any of the ill-gotten gains resulting from the overpayments made by Plaintiff and the members of the Damages Class for Vascepa manufactured by Defendants

during the Class Period.

218. It would be futile for Plaintiff and Damages Class members to seek to exhaust any remedy against the immediate intermediary in the chain of distribution from which they indirectly purchased Vascepa, as those intermediaries are not liable and would not compensate Plaintiff and Damages Class members for Defendants' unlawful conduct.

219. The economic benefit Defendants derived from overcharging Plaintiff and Damages Class members for Vascepa is a direct and proximate result of Defendants' unlawful and anticompetitive practices.

220. The financial benefits Defendants derived are ill-gotten gains that rightfully belong to Plaintiff and Damages Class members, who paid and continue to pay artificially inflated prices that inured to Defendants' benefit.

221. It would be inequitable under unjust enrichment principles under the laws of the states described below for Defendants to retain any of the overcharges Plaintiff and Damages Class members paid for Vascepa that were derived from Defendants' unfair, anticompetitive, and unlawful methods, acts, and trade practices.

222. Defendants are aware of and appreciate the benefits that Plaintiff and the Damages Class members have bestowed upon it.

223. Defendants should be ordered to disgorge all unlawful or inequitable proceeds it received in a common fund for the benefit of Plaintiff and Damages Class members, who collectively have no adequate remedy at law.

224. A constructive trust should be imposed upon all unlawful or inequitable sums Defendants received, which arise from overpayments for brandand generic versions of Vascepa by Plaintiff and the Damages Class members.

225. Plaintiff and Damages Class members have no adequate remedy at law.

226. By engaging in the foregoing unlawful or inequitable conduct, which deprived Plaintiff and the Damages Class members of the opportunity to purchase lower-priced generic versions of Vascepa and forced them to pay higher prices for brand and generic versions of Vascepa, Defendants has been unjustly enriched in violation of the common law of various states and commonwealths, as outlined below:

Alabama

227. Defendants unlawfully overcharged end-payers who made purchases of or reimbursements for brand and generic versions of Vascepa in Alabama at prices that were more than they would have been but for Defendants' actions.

228. Plaintiff and Damages Class members have conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of Plaintiff and Damages Class members.

229. Defendants accepted and retained the benefits bestowed upon them under inequitable and unjust circumstances arising from unlawful overcharges to Plaintiff and Damages Class members.

230. Defendants have benefitted at the expense of Plaintiff and Damages Class members from revenue resulting from unlawful overcharges for brand and generic versions of Vascepa.

Alaska

231. Defendants unlawfully overcharged end-payers who made purchases of or reimbursements for brand and generic versions of Vascepa in Alaska at prices that were more than they would have been but for Defendants' actions.

232. Plaintiff and Damages Class members have conferred an economic benefit upon

Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of Plaintiff and Damages Class members.

233. Defendants appreciated the benefits bestowed upon them by Plaintiff and Damages Class members.

234. Defendants accepted and retained the benefits bestowed upon them under inequitable and unjust circumstances arising from unlawful overcharges to Plaintiff and Damages Class members.

235. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating Plaintiff and Damages Class members.

236. Defendants have benefitted at the expense of Plaintiff and Damages Class members from revenue resulting from unlawful overcharges for brand and generic versions of Vascepa.

Arizona

237. Defendants unlawfully overcharged end-payers, who made purchases of or reimbursements for brand and generic versions of Vascepa in Arizona at prices that were more than they would have been but for Defendants' actions.

238. Defendants have been enriched by revenue resulting from unlawful overcharges for brand and generic versions of Vascepa.

239. Plaintiff have been impoverished by the overcharges for brand and generic versions of Vascepa resulting from Defendants' unlawful conduct.

240. Defendants' enrichment and Plaintiff's impoverishment are connected. Defendants have paid no consideration to any other person for any benefits they received from Plaintiff and Damages Class Members.

241. There is no justification for Defendants' receipt of the benefits causing its

enrichment and Plaintiff's impoverishment, because Plaintiff paid anticompetitive prices that inured to Defendants' benefit, and it would be inequitable for Defendants to retain any revenue gained from its unlawful overcharges.

242. Plaintiff and Damages Class members have no remedy at law.

Arkansas

243. Defendants unlawfully overcharged end-payers, who made purchases of or reimbursements for brand and generic versions of Vascepa in Arkansas at prices that were more than they would have been but for Defendants' actions.

244. Defendants received money from Plaintiff and Damages Class members as a direct result of the unlawful overcharges and have retained this money.

245. Defendants have paid no consideration to any other person in exchange for this money.

246. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating Plaintiff and Damages Class members.

California

247. Defendants unlawfully overcharged end-payers, who made purchases of or reimbursements for brand and generic versions of Vascepa in California at prices that were more than they would have been but for Defendants' actions.

248. Plaintiff and Damages Class members have conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of Plaintiff and Class members.

249. Defendants retained the benefits bestowed upon them under inequitable and unjust circumstances at the expense of Plaintiff and Damages Class members.

Colorado

250. Defendants unlawfully overcharged end-payers, who made purchases of or reimbursements for brand and generic versions of Vascepa in Colorado at prices that were more than they would have been but for Defendant's actions.

251. Defendants has received a benefit from Plaintiff and Damages Class members in the nature of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of Defendants.

252. Defendants have benefitted at the expense of Plaintiff and Damages Class members.

253. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating Plaintiff and Damages Class members.

Connecticut

254. Defendants unlawfully overcharged end-payers, who made purchases of or reimbursements for brand and generic versions of Vascepa in Connecticut at prices that were more than they would have been but for Defendants' actions.

255. Defendants benefitted in the nature of revenue resulting from unlawful overcharges to the economic detriment of Plaintiff and Damages Class members.

256. Defendants have paid no consideration to any other person in exchange for this benefit.

257. Defendants retained the benefits bestowed upon it under inequitable and unjust circumstances at the expense of Plaintiff and Damages Class members.

Delaware

258. Defendants unlawfully overcharged end-payers, who made purchases of or

reimbursements for brand and generic versions of Vascepa in Delaware at prices that were more than they would have been but for Defendants' actions.

259. Defendants have been enriched by revenue resulting from unlawful overcharges for brand and generic versions of Vascepa.

260. Plaintiff and Damages Class members have been impoverished by the overcharges for brand and generic versions of Vascepa resulting from Defendants' unlawful conduct.

261. Defendants' enrichment and Plaintiff's impoverishment are connected.

262. There is no justification for Defendants' receipt of the benefits causing their enrichment, because Plaintiff and Damages Class members paid supra-competitive prices that inured to Defendants' benefit, and it would be inequitable for Defendants to retain any revenue gained from their unlawful overcharges.

263. Plaintiff and Damages Class members have no remedy at law.

Florida

264. Defendants unlawfully overcharged end-payers, who made purchases of or reimbursements for brand and generic versions of Vascepa in Florida at prices that were more than they would have been but for Defendants' actions.

265. Plaintiff and the Damages Class Members have conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of Plaintiff and the Damages Class members.

266. Defendants appreciated the benefits bestowed upon them by Plaintiff and the Damages Class members.

267. It is inequitable for Defendants to accept and retain the benefits received without compensating Plaintiff and the Damages Class members.

Georgia

268. Defendants unlawfully overcharged end-payers, who made purchases of or reimbursements for brand and generic versions of Vascepa in Georgia at prices that were more than they would have been but for Defendants' actions.

269. Plaintiff and Damages Class members have conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of Plaintiff and Damages Class members.

270. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating Plaintiff and Damages Class members.

Hawaii

271. Defendants unlawfully overcharged end-payers, who made purchases of or reimbursements for brand and generic versions of Vascepa in Hawaii at prices that were more than they would have been but for Defendants' actions.

272. Plaintiff and Damages Class members have conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of Plaintiff and Class members.

273. It is unjust for Defendants to retain the benefits received without compensating Plaintiff and Damages Class members.

Idaho

274. Defendants unlawfully overcharged end-payers, who made purchases of or reimbursements for brand and generic versions of Vascepa in Idaho at prices that were more than they would have been but for Defendants' actions.

275. Plaintiff and Damages Class members have conferred an economic benefit upon

Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of Plaintiff and Damages Class members.

276. Defendants appreciated the benefit conferred upon them by Plaintiff and Damages Class members.

277. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating Plaintiff and Damages Class members.

Illinois

278. Defendants unlawfully overcharged end-payers, who made purchases of or reimbursements for brand and generic versions of Vascepa in Illinois at prices that were more than they would have been but for Defendants' actions.

279. Plaintiff and Damages Class members have conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of Plaintiff and Damages Class members.

280. Defendants retained the benefits bestowed upon them under unjust circumstances arising from unlawful overcharges to Plaintiff and Damages Class members.

281. It is unjust and inequitable for Defendants to retain the benefits received without compensating Plaintiff and Damages Class members.

Iowa

282. Defendants unlawfully overcharged end-payers, who made purchases of or reimbursements for brand and generic versions of Vascepa in Iowa at prices that were more than they would have been but for Defendants' actions.

283. Defendants have been enriched by revenue resulting from unlawful overcharges for brand and generic versions of Vascepa, which revenue resulted from anticompetitive prices paid

by Plaintiff and the Damages Class members, which inured to Defendants' benefit.

284. Defendants' enrichment has occurred at the expense of Plaintiff and Damages Class members.

285. It is against equity and good conscience for Defendants to be permitted to retain the revenue resulting from their unlawful overcharges.

Kansas

286. Defendants unlawfully overcharged end-payers, who made purchases of or reimbursements for brand and generic versions of Vascepa in Kansas at prices that were more than they would have been but for Defendants' actions.

287. Plaintiff and Damages Class members have conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of Plaintiff and Damages Class members.

288. Defendants retained the benefits bestowed upon them under unjust circumstances arising from unlawful overcharges to Plaintiff and Damages Class members.

289. Defendants were unjustly enriched at the expense of Plaintiff and Damages Class members.

Kentucky

290. Defendants unlawfully overcharged end-payers, who made purchases of or reimbursements for brand and generic versions of Vascepa in Kentucky at prices that were more than they would have been but for Defendants' actions.

291. Plaintiff and Damages Class members have conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of Plaintiff and Damages Class members.

292. Defendants appreciated the benefit conferred upon them by Plaintiff and Damages Class members.

293. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating Plaintiff and Damages Class members.

Louisiana

294. Defendants unlawfully overcharged end-payers, who made purchases of or reimbursements for brand and generic versions of Vascepa in Louisiana at prices that were more than they would have been but for Defendants' actions.

295. Defendants have been enriched by revenue resulting from unlawful overcharges for brand and generic versions of Vascepa.

296. Plaintiff and Damages Class members have been impoverished by the overcharges for brand and generic versions of Vascepa resulting from Defendants' unlawful conduct.

297. Defendants' enrichment and Plaintiff's impoverishment are connected.

298. There is no justification for Defendants' receipt of the benefits causing their enrichment, because Plaintiff and Damages Class members paid supra-competitive prices that inured to Defendants' benefit, and it would be inequitable for Defendants to retain any revenue gained from its unlawful overcharges.

299. Plaintiff and Damages Class members have no other remedy at law.

Maine

300. Defendants unlawfully overcharged end-payers, who made purchases of or reimbursements for brand and generic versions of Vascepa in Maine at prices that were more than they would have been but for Defendants' actions.

301. Plaintiff and Damages Class members have conferred an economic benefit upon

Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of Plaintiff and Damages Class members.

302. Defendants retained the benefits bestowed upon them under unjust circumstances arising from unlawful overcharges to Plaintiff and Damages Class members.

303. Defendants were aware of and appreciated the benefit bestowed upon them by Plaintiff and Damages Class members.

304. Defendants were unjustly enriched at the expense of Plaintiff and Damages Class members.

Maryland

305. Defendants unlawfully overcharged end-payers, who made purchases of or reimbursements for brand and generic versions of Vascepa in Maryland at prices that were more than they would have been but for Defendants' actions.

306. Plaintiff and Damages Class members have conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of Plaintiff and Damages Class members.

307. Defendants were aware of or appreciated the benefit bestowed upon them by Plaintiff and Damages Class members.

308. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating Plaintiff and Damages Class members.

Massachusetts

309. Defendants unlawfully overcharged end-payers, who made purchases of or reimbursements for brand and generic versions of Vascepa in Massachusetts at prices that were more than they would have been but for Defendants' actions.

310. Plaintiff and Damages Class members have conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of Plaintiff and Damages Class members.

311. Defendants were aware of or appreciated the benefit conferred upon them by Plaintiff and Damages Class members.

312. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating Plaintiff and Damages Class members. Fairness and good conscience require that Defendants not be permitted to retain the revenue resulting from its unlawful overcharges at the expense of Plaintiff and Damages Class members.

Michigan

313. Defendants unlawfully overcharged end-payers, who made purchases of or reimbursements for brand and generic versions of Vascepa in Michigan at prices that were more than they would have been but for Defendants' actions.

314. Plaintiff and Damages Class members have conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of Plaintiff and Damages Class members.

315. Defendants retained the benefits bestowed upon them under unjust circumstances arising from unlawful overcharges to Plaintiff and Damages Class members.

316. Defendants were unjustly enriched at the expense of Plaintiff and Damages Class members.

Minnesota

317. Defendants unlawfully overcharged end-payers, who made purchases of or reimbursements for brand and generic versions of Vascepa in Minnesota at prices that were more

than they would have been but for Defendants' actions.

318. Defendants appreciated and knowingly accepted the benefits bestowed upon them by Plaintiff and Damages Class members. Defendants have paid no consideration to any other person for any of the benefits it has received from Plaintiff and Damages Class members.

319. It is inequitable for Defendants to accept and retain the benefits received without compensating Plaintiff and Damages Class members.

Mississippi

320. Defendants unlawfully overcharged end-payers, who made purchases of or reimbursements for brand and generic versions of Vascepa in Mississippi at prices that were more than they would have been but for Defendants' actions.

321. Defendants retained the benefit of overcharges received on the sales of brand and generic versions of Vascepa, which in equity and good conscience belong to Plaintiff and Damages Class members on account of Defendants' anticompetitive conduct.

Missouri

322. Defendants unlawfully overcharged end-payers, who made purchases of or reimbursements for brand and generic versions of Vascepa in Missouri at prices that were more than they would have been but for Defendants' actions.

323. Plaintiff and Damages Class members have conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of Plaintiff and Damages Class members.

324. Defendants appreciated the benefit bestowed upon them by Plaintiff and Damages Class members.

325. Defendants accepted and retained the benefit bestowed upon them under

inequitable and unjust circumstances arising from unlawful overcharges to Plaintiff and Damages Class members.

Montana

326. Defendants unlawfully overcharged end-payers, who made purchases of or reimbursements for brand and generic versions of Vascepa in Montana at prices that were more than they would have been but for Defendants' actions.

327. Plaintiff and Damages Class members have conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of Plaintiff and Damages Class members.

328. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating Plaintiff and Damages Class members.

Nebraska

329. Defendants unlawfully overcharged end-payers, who made purchases of or reimbursements for brand and generic versions of Vascepa in Nebraska at prices that were more than they would have been but for Defendants' actions.

330. Defendants received money from Plaintiff and Damages Class members as a direct result of the unlawful overcharges, and have retained this money. Defendants have paid no consideration to any other person in exchange for this money.

331. In justice and fairness, Defendants should disgorge such money and remit the overcharged payments back to Plaintiff and Damages Class members.

Nevada

332. Defendants unlawfully overcharged end-payers, who made purchases of or reimbursements for brand and generic versions of Vascepa in Nevada at prices that were more than

they would have been but for Defendants' actions.

333. Plaintiff and Damages Class members have conferred an economic benefit upon Defendants in the nature of revenue resulting from unlawful overcharges for brand and generic versions of Vascepa.

334. Defendants appreciated the benefits bestowed upon them by Plaintiff and Damages Class members, for which they have paid no consideration to any other person.

335. Defendants knowingly accepted and retained the benefits bestowed upon them by Plaintiff and Damages Class members.

336. The circumstances under which Defendants have accepted and retained the benefits bestowed upon them by Plaintiff and Damages Class members are inequitable in that they result from Defendants' unlawful overcharges for brand and generic versions of Vascepa.

New Hampshire

337. Defendants unlawfully overcharged end-payers, who made purchases of or reimbursements for brand and generic versions of Vascepa in New Hampshire at prices that were more than they would have been but for Defendants' actions.

338. Defendants have received a benefit from Plaintiff and Damage Class members in the nature of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of Defendants.

339. Under the circumstances, it would be unconscionable for Defendants to retain such benefits.

New Jersey

340. Defendants unlawfully overcharged end-payers, who made purchases of or reimbursements for brand and generic versions of Vascepa in New Jersey at prices that were more

than they would have been but for Defendants' actions.

341. Defendants have received a benefit from Plaintiff and Damages Classmembers in the nature of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of Defendants.

342. The benefits conferred upon Defendants were not gratuitous, in that they comprised revenue created by unlawful overcharges arising from arising from unlawful overcharges to Plaintiff and Damages Class members.

343. Defendants have paid no consideration to any other person for any of the unlawful benefits they received from Plaintiff and Damages Class members with respect to Defendants' sales of brand and generic versions of Vascepa.

344. Under the circumstances, it would be unjust for Defendants to retain such benefits without compensating Plaintiff and Damages Class members.

New Mexico

345. Defendants unlawfully overcharged end-payers, who made purchases of or reimbursements for brand and generic versions of Vascepa in New Mexico at prices that were more than they would have been but for Defendants' actions.

346. Defendants have knowingly benefitted at the expense of Plaintiff and Damages Class members from revenue resulting from unlawful overcharges for brand and generic versions of Vascepa.

347. To allow Defendants to retain the benefits would be unjust because the benefits resulted from anticompetitive pricing that inured to Defendants' benefit and because Defendants have paid no consideration to any other person for any of the benefits it received.

New York

348. Defendants unlawfully overcharged end-payers, who made purchases of or reimbursements for brand and generic versions of Vascepa in New York at prices that were more than they would have been but for Defendants' actions.

349. Defendants have been enriched by revenue resulting from unlawful overcharges for brand and generic versions of Vascepa, which revenue resulted from anticompetitive prices paid by Plaintiff and Damages Class members, which inured to Defendants' benefit.

350. Defendants' enrichment has occurred at the expense of Plaintiff and Damages Class members.

351. It is against equity and good conscience for Defendants to be permitted to retain the revenue resulting from its unlawful overcharges.

North Carolina

352. Defendants unlawfully overcharged end-payers, who made purchases of or reimbursements for brand and generic versions of Vascepa in North Carolina at prices that were more than they would have been but for Defendants' actions.

353. Plaintiff and Damages Class members have conferred an economic benefit upon Defendants in the nature of revenue resulting from unlawful overcharges to the economic detriment of Plaintiff and Damages Class members.

354. Plaintiff did not interfere with Defendants' affairs in any manner that conferred these benefits upon Defendants.

355. The benefits conferred upon Defendants were not gratuitous, in that they comprised revenue created by unlawful overcharges arising from Defendants' actions to delay entry of generic versions of Vascepa to the market.

356. The benefits conferred upon Defendants are measurable, in that the revenue Defendants has earned due to unlawful overcharges are ascertainable by review of sales records and documents relating to Defendants' anticompetitive conduct.

357. Defendants consciously accepted the benefits and continues to do so as of the date of this filing.

North Dakota

358. Defendants unlawfully overcharged end-payers, who made purchases of or reimbursements for brand and generic versions of Vascepa in North Dakota at prices that were more than they would have been but for Defendants' actions.

359. Defendants have been enriched by revenue resulting from unlawful overcharges for brand and generic versions of Vascepa.

360. Plaintiff and the members of the Class have been impoverished by the overcharges for brand and generic versions of Vascepa resulting from Defendants' unlawful conduct.

361. Defendants' enrichment and Plaintiff's impoverishment are connected. Defendants have paid no consideration to any other person for any benefits they received directly or indirectly from Plaintiff and Damages Class members.

362. There is no justification for Defendants' receipt of the benefits causing their enrichment, because Plaintiff and Damages Class members paid anticompetitive prices that inured to Defendants' benefit, and it would be inequitable for Defendants to retain any revenue gained from their unlawful overcharges.

363. Plaintiff and Damages Class members have no remedy at law.

Oklahoma

364. Defendants unlawfully overcharged end-payers, who made purchases of or

reimbursements for brand and generic versions of Vascepa in Oklahoma at prices that were more than they would have been but for Defendants' actions.

365. Defendants received money from Plaintiff and Damages Class members as a direct result of the unlawful overcharges and have retained this money.

366. Defendants have paid no consideration to any other person in exchange for this money.

367. Plaintiff and Damages Class members have no remedy at law.

368. It is against equity and good conscience for Defendants to be permitted to retain the revenue resulting from their unlawful overcharges.

Oregon

369. Defendants unlawfully overcharged end-payers, who made purchases of or reimbursements for brand and generic versions of Vascepa in Oregon at prices that were more than they would have been but for Defendants' actions.

370. Plaintiff and Damages Class members have conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of Plaintiff and Damages Class members.

371. Defendants were aware of the benefit bestowed upon it by Plaintiff and Damages Class members.

372. It would be inequitable and unjust for Defendants to retain any of the overcharges for Vascepa derived from Defendants' unfair conduct without compensating Plaintiff and Class members.

Pennsylvania

373. Defendants unlawfully overcharged end-payers, who made purchases of or

reimbursements for brand and generic versions of Vascepa in Pennsylvania at prices that were more than they would have been but for Defendants' actions.

374. Plaintiff and Damages Class members have conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of Plaintiff and Damages Class members.

375. Defendants appreciated the benefit bestowed upon them by Plaintiff and Damages Class members.

376. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating Plaintiff and Damages Class members.

Rhode Island

377. Defendants unlawfully overcharged end-payers, who made purchases of or reimbursements for brand and generic versions of Vascepa in Rhode Island at prices that were more than they would have been but for Defendants' actions.

378. Plaintiff and Damages Class members have conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of Plaintiff and Damages Class members.

379. Defendants were aware of and/or recognized the benefit bestowed upon them by Plaintiff and the Damages Class members.

380. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating Plaintiff and Damages Class members.

South Carolina

381. Defendants unlawfully overcharged end-payers, who made purchases of or reimbursements for brand and generic versions of Vascepa in South Carolina at prices that were

more than they would have been but for Defendants' actions.

382. The benefits conferred upon Defendants were not gratuitous, in that they comprised revenue created by unlawful overcharges to Plaintiff and Damages Class members.

383. Defendants realized value from the benefit bestowed upon them by Plaintiff and Damages Class members.

384. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating Plaintiff and Damages Class members.

South Dakota

385. Defendants unlawfully overcharged end-payers, who made purchases of or reimbursements for brand and generic versions of Vascepa in South Dakota at prices that were more than they would have been but for Defendants' actions.

386. Plaintiff and Damages Class members have conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of Plaintiff and Damages Class members.

387. Defendants were aware of the benefit bestowed upon them by Plaintiff and Damages Class members.

388. Under the circumstances, it would be inequitable and unjust for Defendants to retain such benefits without reimbursing Plaintiff and Damages Class members.

Tennessee

389. Defendants unlawfully overcharged end-payers, who made purchases of or reimbursements for brand and generic versions of Vascepa in Tennessee at prices that were more than they would have been but for Defendants' actions.

390. Plaintiff and Damages Class members have conferred an economic benefit upon

Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of Plaintiff and Damages Class members.

391. Defendants were aware of or appreciated the benefit bestowed upon them by Plaintiff and Damages Class members.

392. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating Plaintiff and Damages Class members.

393. It would be futile for Plaintiff and Damages Class members to exhaust all remedies against the entities with which Plaintiff and Damages Class members have privity of contract because Plaintiff and Damages Class members did not purchase brand or generic versions of Vascepa directly from Defendants.

Texas

394. Defendants unlawfully overcharged end-payers, who made purchases of or reimbursements for brand and generic versions of Vascepa in Texas at prices that were more than they would have been but for Defendants' actions.

395. Defendants have received a benefit from Plaintiff and Damages Class members in the nature of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of Defendants.

396. Defendants were aware of or appreciated the benefit bestowed upon them by Plaintiff and Damages Class members.

397. The circumstances under which Defendants have retained the benefits bestowed upon them by Plaintiff and Damages Class members are inequitable in that they result from Defendants' unlawful overcharges for brand and generic versions of Vascepa.

398. Plaintiff and Damages Class members have no remedy at law.

Utah

399. Defendants unlawfully overcharged end-payers, who made purchases of or reimbursements for brand and generic versions of Vascepa in Utah at prices that were more than they would have been but for Defendants' actions.

400. Plaintiff and Damages Class members have conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of Plaintiff and Damages Class members.

401. Defendants were aware of or appreciated the benefit bestowed upon them by Plaintiff and Damages Class members.

402. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating Plaintiff and Damages Class members.

Vermont

403. Defendants unlawfully overcharged end-payers, who made purchases of or reimbursements for brand and generic versions of Vascepa in Vermont at prices that were more than they would have been but for Defendants' actions.

404. Plaintiff and Damages Class members have conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of Plaintiff and Damages Class members.

405. Defendants accepted the benefit bestowed upon them by Plaintiff and Damages Class members.

406. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating Plaintiff and Damages Class members.

Virginia

407. Defendants unlawfully overcharged end-payers, who made purchases of or reimbursements for brand and generic versions of Vascepa in Virginia at prices that were more than they would have been but for Defendants' actions.

408. Plaintiff and Damages Class members have conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of Plaintiff and Damages Class members.

409. Defendants was aware of the benefit bestowed upon them.

410. Defendants should reasonably have expected to repay Plaintiff and Damages Class members.

411. The benefits conferred upon Defendants were not gratuitous, in that they constituted revenue created by unlawful overcharges arising from Defendants' illegal and unfair actions to inflate the prices of brand and generic versions of Vascepa.

412. Defendants have paid no consideration to any other person for any of the benefits they have received from Plaintiff and Damages Class members.

Washington

413. Defendants unlawfully overcharged end-payers, who made purchases of or reimbursements for brand and generic versions of Vascepa in Washington at prices that were more than they would have been but for Defendants' actions.

414. Plaintiff and the Damages Class members have conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of Plaintiff and Damages Class members.

415. Defendants were aware of or appreciated the benefit conferred upon them by

Plaintiff and Damages Class members.

416. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating Plaintiff and Damages Class members.

West Virginia

417. Defendants unlawfully overcharged end-payers, who made purchases of or reimbursements for brand and generic versions of Vascepa in West Virginia at prices that were more than they would have been but for Defendants' actions.

418. Plaintiff and Damages Class members have conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of Plaintiff and Damages Class members.

419. Defendants were aware of or appreciated the benefit bestowed upon them by Plaintiff and Damages Class members.

420. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating Plaintiff and Damages Class members.

Wisconsin

421. Defendants unlawfully overcharged end-payers, who made purchases of or reimbursements for brand and generic versions of Vascepa in Wisconsin at prices that were more than they would have been but for Defendants' actions.

422. Plaintiff and Damages Class members have conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of Plaintiff and Damages Class members.

423. Defendants appreciated the benefit bestowed upon them by Plaintiff and Damages Class members.

424. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating Plaintiff and Damages Class members.

Wyoming

425. Defendants unlawfully overcharged end-payers, who made purchases of or reimbursements for brand and generic versions of Vascepa in Wyoming at prices that were more than they would have been but for Defendants' actions.

426. Plaintiff and Damages Class members have conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of Plaintiff and Damages Class members.

427. Defendants accepted, used, and enjoyed the benefits bestowed upon them by Plaintiff and Damages Class members.

428. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating Plaintiff and Damages Class members.

District of Columbia

429. Defendants unlawfully overcharged end-payers, who made purchases of or reimbursements for brand and generic versions of Vascepa in the District of Columbia at prices that were more than they would have been but for Defendants' actions.

430. Plaintiff and Damages Class members have conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of Plaintiff and Damages Class members.

431. Defendants accepted and retained the benefit bestowed upon them under inequitable and unjust circumstances arising from unlawful overcharges to Plaintiff and Damages Class members.

432. Under the circumstances, it would be inequitable and unjust for Defendants to retain such benefits.

Puerto Rico

433. Defendants unlawfully overcharged end-payers, who made purchases of or reimbursements for brand and generic versions of Vascepa in Puerto Rico at prices that were more than they would have been but for Defendants' actions.

434. Defendants have been enriched by revenue resulting from unlawful overcharges for brand and generic versions of Vascepa.

435. Plaintiff have been impoverished by the overcharges for brand and generic versions of Vascepa resulting from Defendants' unlawful conduct.

436. Defendants' enrichment and Plaintiff's impoverishment are connected.

437. There is no justification for Defendants' receipt of the benefits causing its enrichment and Plaintiff's impoverishment, because Plaintiff and Damages Class members paid anticompetitive prices that inured to Defendants' benefit, and it would be inequitable for Defendants to retain any revenue gained from their unlawful overcharges.

438. Plaintiff and Damages Class members have no remedy at law.

COUNT FOUR

**Violation of Section 1 of the Sherman Act:
Contract, Combination, and Conspiracy in Restraint of Trade**

439. Plaintiff incorporates by reference all of the allegations above as though fully set forth herein.

440. Plaintiff brings this claim on behalf of the Injunctive Relief Class.

441. Defendants violated 15 U.S.C. § 1 by entering into a series of exclusive contracts that were intended to and did lock up supply of Vascepa API, thereby constraining competition

in the market for brand and generic Vascepa.

442. The agreements between Amarin and each of its API-suppliers substantially, unreasonable, and unduly restrained trade in the relevant market, the purpose and effect of which was to:

- a. prevent generic competitors from obtaining the API necessary to manufacture Vascepa;
- b. delay the entry of generic versions of Vascepa;
- c. hamper the ability of generic competitors to meet demand for their generic Vascepa product; and
- d. raise and maintain the prices that Plaintiff and the Injunction Class members would pay for Vascepa to and at supra-competitive levels.

443. There is no legitimate, non-pretextual, procompetitive business justification for the exclusive contracts between Amarin and the API-suppliers.

444. The agreements between Amarin and each of the API-suppliers harmed competition in the relevant market.

445. As a direct and proximate result of Defendant's violation of Sherman Act § 1, Plaintiff and the Injunction Class have been injured in their business and property throughout the Class Period.

446. Plaintiff and the Injunction Class are entitled to injunctive and other equitable relief, pursuant to 15 U.S.C. § 26.

COUNT FIVE
Violation of Section 2 of the Sherman Act: Monopolization

447. Plaintiff incorporates by reference all of the allegations above as though fully set forth herein.

448. Plaintiff brings this claim on behalf of the Injunctive Relief Class.

449. As described above, throughout the relevant time period Amarin possessed

monopoly power nationwide and in each of the United States and its territories in the market for Vascepa. No other manufacturer sold a competing version of Vascepa during the relevant time period.

450. At all relevant times, Amarin possessed substantial market power (*i.e.*, monopoly power) in the relevant market. Amarin possessed the power to control prices in, prevent prices from falling in, and exclude competitors from the relevant market.

451. Through their overarching anticompetitive scheme, as alleged above, Amarin willfully maintained their monopoly power in the relevant market using restrictive or exclusionary conduct, rather than by means of greater business acumen or a historic accident, and thereby injured Plaintiff and the InjunctiveRelief Class. Amarin's anticompetitive conduct was done with the specific intent to maintain their monopoly in the market for Vascepa in the United States and its territories.

452. Amarin knowingly and intentionally engaged in this anticompetitive scheme to monopolize the market for Vascepa and its generic equivalents as described above. Amarin accomplished this scheme by, *inter alia*, (1) entering into exclusive supply agreements with at least four different icosapent ethyl API suppliers; (2) otherwise foreclosing the supply of icosapent ethyl API; and (3) raising and maintaining prices so that Plaintiff and Class members would pay for Vascepa at supra-competitive prices.

453. The goal, purpose, and effect of Amarin's scheme was to prevent, delay, and limit the sale of generic Vascepa in the United States at prices significantly below Amarin's prices for Vascepa, thereby effectively preventing the average market price of Vascepa and its generic equivalents from declining dramatically while maintaining and extending its monopoly power with respect to Vascepa.

454. Plaintiff and members of the Injunctive Relief Class purchased substantial amounts of Vascepa indirectly from Amarin.

455. As a result of Amarin's illegal conduct, Plaintiff and members of the Injunctive Relief Class were compelled to pay, and did pay, more than they would have paid for their requirements of Vascepa and its generic equivalents absent Amarin's illegal conduct. But for Amarin's illegal conduct, competitors would have begun selling generic Vascepa during the relevant period, and prices for Vascepa and its generic equivalents would have been lower, sooner.

456. Had manufacturers of generic Vascepa entered the market and lawfully competed with Amarin earlier, Plaintiff and other members of the Injunctive Relief Class would have substituted lower-priced generic Vascepa for the higher-priced brand-name Vascepa for some or all of their requirements of Vascepa and its generic equivalents, and/or would have paid lower net prices on their remaining Vascepa and/or AB-rated bioequivalent purchases.

457. Plaintiff and members of the Injunctive Relief Class will continue to suffer injury, in the form of overcharges paid for Vascepa, if Amarin's unlawful conduct is not enjoined.

458. Plaintiff and the members of the Injunctive Relief Class therefore seek equitable and injunctive relief under Section 16 of the Clayton Act, 15 U.S.C. § 26, and other applicable laws, to correct for the anticompetitive market effects caused by Amarin's unlawful conduct, and to assure that similar anticompetitive conduct and effects do not continue or reoccur in the future.

RELIEF SOUGHT

WHEREFORE, Plaintiff, on its own behalf and on behalf of the proposed Classes, prays for judgment against Defendants and that this Court:

1. Determine that this action may be maintained as a class action pursuant to Rules

23(a), (b)(2) and (b)(3) of the Federal Rules of Civil Procedure, and direct that reasonable notice of this action, as provided by Rule 23(c)(2), be given to the Classes, and appoint Plaintiff as the named representative of the Classes;

2. Award Plaintiff and the Damages Class treble damages (*i.e.*, three times overcharges) in an amount to be determined at trial, plus interest in accordance with law;
3. Grant Plaintiff and the Injunctive Relief Class equitable relief in the nature of disgorgement, restitution, and the creation of a constructive trust to remedy Defendants' unjust enrichment;
4. Award Plaintiff and the Classes their costs of suit, including reasonable attorneys' fees as provided by law;
5. Permanently enjoin Defendants both from continuing the unlawful conduct alleged here, and from engaging in similar or related conduct in the future; and
6. Award such other and further relief as the Court deems just and proper.

JURY DEMAND

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Plaintiff, on behalf of itself and the proposed Class, demands a trial by jury of all issues so triable.

**LITE DEPALMA GREENBERG
& AFANADOR LLC**

Dated: August 5, 2021

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**Pro Hac Vice Application to be filed*

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Counsel for Plaintiff

LOCAL CIVIL RULE 11.2 CERTIFICATION

Pursuant to Local Civil Rule 11.2, I hereby certify that the matter in controversy is related to the following civil actions:

- *Uniformed Fire Association Family Protection Plan Local 854*, 3:21-cv-12061 (ZNQ)(LHG) (D.N.J.) filed June 2, 2021;
- *Welfare Plan of the International Union of Operating Engineers, Local 137, 137a, 137b, 137c and 137r*, 3:21-cv-12416 (ZNQ)(LHG) (D.N.J.) filed June 11, 2021; and
- *Local 464a United Food and Commercial Workers Union Welfare Service Benefit Fund*, 3:21-cv-13009 (ZNQ)(LHG) (D.N.J.) filed June 25, 2021.

I hereby certify that the following statements made by me are true. I am aware that if any of the foregoing statements made by me are willfully false, I am subject to punishment.

Dated: August 5, 2021

**LITE DEPALMA GREENBERG
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